

# Exhibit A

REDACTED

1 UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY  
2  
3 IN RE: VALSARTAN, )  
LOSARTAN, AND IRBESARTAN )  
4 PRODUCTS LIABILITY )  
LITIGATION )  
5 \_\_\_\_\_ ) MDL NO. 2875  
HON. ROBERT B. KUGLER  
6 THIS DOCUMENT RELATES TO )  
ALL CASES )  
7 )  
8

9 CONFIDENTIAL INFORMATION - SUBJECT TO  
10 PROTECTIVE ORDER  
11

12 VIDEOTAPED DEPOSITION OF:  
13 MICHAEL BOTTORFF, PHARM.D.  
14 Taken on behalf of the Plaintiffs  
15 March 25, 2022  
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<p style="text-align: right;">Page 2</p> <p>1 REMOTE APPEARANCES:                  2 For the Plaintiffs:                  3 C. BRETT VAUGHN, ESQ.                  Hollis Law Firm                  4 8101 College Boulevard                  Suite 260                  5 Overland Park, Kansas 66210                  6 For the Defendants, Teva Pharmaceutical                  Industries, Ltd., Teva Pharmaceuticals                  7 SA, Inc., Actavis LLC, and Actavis Pharma, Inc.:                  STEPHEN T. FOWLER, ESQ.                  8 Greenberg Traurig, LLP                  2101 L Street, N.W.                  Suite 1000                  9 Washington, D.C. 20037                  202.331.3100                  10 Fowlerst@gtlaw.com                  11                  Also Present Remotely:                  12 Alice Springer                  13 Bailey Hughes                  Christine Gannon                  14 Daniela Tenjidor                  Geoffrey Coan                  15 George Williamson                  Gerond Lawrence                  16 Iris Simpson                  Ken Dzikowski                  17 Marlene J. Goldenberg                  Melissa Catello                  18 Melisha Valenzuela                  William Murtha                  19 Phillip Todd - Videographer                  20                  21                  22                  23                  24                  25</p>	<p style="text-align: right;">Page 4</p> <p>1 Exhibit 12 Document Torrent-MDL 145 25                  2875-00259489                  2                  Exhibit 13 Document 149 21                  3 RO-MDL-2875-0061940                  4 Exhibit 14 Document 158 2                  RO-MDL-2875-0004639                  5                  Exhibit 15 RO-MDL- 2875-0026534 165 7                  6                  Exhibit 16 Document 168 21                  7 RO-MDL-2875-0080263                  8 Exhibit 17 Document 175 1                  9 Mylan-MDL-2875-00001448                  Exhibit 18 Document Mylan-MDL 175 5                  10 2875-00031265                  11 Exhibit 19 "PRACS Cetero Bankruptcy" 176 2                  Article                  12                  Exhibit 20 FDA letter to Cetero 177 5                  13 Research                  14 Exhibit 21 "Teva and Cipla will have 182 21                  ANDAs Withdrawn" Article                  15                  Exhibit 22 Document Teva-MDL- 185 14                  16 2875-00003105                  17 Exhibit 23 Document Teva-MDL- 187 13                  2875-00003194                  18                  Exhibit 24 Document Teva-MDL- 189 8                  19 2875-00268983                  20 Exhibit 25 Document Teva- MDL 191 18                  2875-00102393                  21                  Exhibit 26 Document ZHP 01453143 197 23                  22                  Exhibit 27 Document Princeton 00179194 199 19                  23                  Exhibit 28 Document Princeton 00134669 202 16                  24                  Exhibit 29 Document Princeton 00369303 207 14                  25</p>
<p style="text-align: right;">Page 3</p> <p>1 I N D E X                  2 Page/Line                  3 THE WITNESS: MICHAEL BOTTORFF, PHARM.D.                  4 EXAMINATION BY MR. VAUGHN 8 9                  EXAMINATION BY MR. FOWLER 241 25                  5 EXAMINATION BY MR. VAUGHN                  6                  7                  8 INDEX OF EXHIBITS                  9 Exhibits Description Page/Line                  10 Exhibit 1 Class Action Expert Report 10 11                  11 Exhibit 2 General Causation Report 10 21                  12 Exhibit 3 Invoices 33 25                  13 Exhibit 4 2011 FDA Guidance for 95 3                  Submission of Summary                  14 Bioequivalence Data for                  ANDAs                  15                  Exhibit 5 FDA's 2021 Draft Guidance 97 3                  16                  Exhibit 6 Notice of Deposition 107 11                  17                  Exhibit 7 Document Teva-MDL 112 20                  18 2875-00808468                  19 Exhibit 8 Document Hetero_USA 124 14                  000029545                  20                  Exhibit 9 Document Hetero_USA 129 18                  21 000005016                  22 Exhibit 10 Document Torrent-MDL 142 25                  287500003049                  23                  Exhibit 11 Document Torrent-MDL 145 21                  24 2875-00003054                  25</p>	<p style="text-align: right;">Page 5</p> <p>1 Exhibit 30 Document Princeton 00153602 210 13                  2 Exhibit 31 EMA Press Release regarding 217 20                  GVK Biosciences                  3                  Exhibit 32 Document ZHP 00378002 220 17                  4                  Exhibit 33 Document Teva-MDL 226 11                  5 2875-00117673                  6 Exhibit 34 Document Bottorff 0001 230 23                  7 Exhibit 35 Defendants' Responses and 242 7                  Objections to Plaintiffs'                  8 Notice of Videotaped Oral                  Deposition Michael                  9 Bottorff, Pharm.D                  Exhibit 36 Curriculum Vitae 242 16                  10                  Exhibit 37 21 CFR 314.3 Definitions 244 14                  11                  Exhibit 38 Materials Considered List 260 9                  12                  Exhibit 39 Flash Drive of Dr. 260 23                  13 Bottorff's Materials                  Considered (late-filed)                  14                  15                  16                  17                  18                  19                  20                  21                  22                  23                  24                  25</p>

<p style="text-align: right;">Page 6</p> <p>1 The videotaped deposition of                  2 MICHAEL BOTTORFF, PHARM.D., was taken by                  3 counsel for the Plaintiffs, on March 25,                  4 2022, commencing at 9:39 a.m. Eastern,                  5 via remote proceedings, for all purposes                  6 under the Tennessee Rules of Civil                  7 Procedure.                  8 The formalities as to notice,                  9 caption, certificate, et cetera, are not                  10 waived. All objections, except as to                  11 the form of the questions, are reserved                  12 to the hearing.                  13 It is agreed that Carissa L.                  14 Boone, being a Notary Public and Court                  15 Reporter, may swear the witness, and                  16 that the reading and signing of the                  17 completed deposition by the witness are                  18 not waived.                  19                  20                  21 * * *                  22                  23                  24                  25</p>	<p style="text-align: right;">Page 8</p> <p>1 MICHAEL BOTTORFF, PHARM.D.                  2 having been first duly sworn, was examined and                  3 testified as follows:                  4 THE VIDEOGRAPHER: I'm sorry, I                  5 did not hear anything from the witness.                  6 I'm sorry, I did not hear                  7 anything from the witness.                  8 THE WITNESS: I said "I do."                  9 EXAMINATION                  10 BY MR. VAUGHN:                  11 Q. All right, Dr. Bottorff. My name                  12 is Brett Vaughn. You remember I took your                  13 deposition about six months ago in the general                  14 causation stage of the personal injury cases,                  15 correct?                  16 A. I do remember you, yes.                  17 Q. And you've now submitted an                  18 expert report for the class action side of this                  19 litigation?                  20 A. Correct.                  21 Q. And did you use your general                  22 causation expert report as the base of your class                  23 action expert report?                  24 A. There was some overlap in what                  25 seemed to be some of the issues between the class</p>
<p style="text-align: right;">Page 7</p> <p>1 THE VIDEOGRAPHER: Good morning.                  2 We are now on the record. My name is                  3 Phillip Todd. I am the videographer for                  4 Golkow Litigation Services.                  5 Today's date is March 25th, 2022,                  6 and the time is 9:39 a.m. Eastern.                  7 This remote video deposition is                  8 being held in the matter of Valsartan,                  9 Losartan and Irbesartan Products                  10 Liability Litigation in the United                  11 States District Court, District of New                  12 Jersey.                  13 The deponent is Dr. Michael                  14 Bottorff.                  15 All parties in this deposition                  16 are appearing remotely and have agreed                  17 to the witness being sworn in remotely.                  18 Due to the nature of remote                  19 reporting, please pause briefly before                  20 speaking to ensure all parties are heard                  21 completely.                  22 Counsel will be noted on the                  23 stenographic record.                  24 The court reporter, Carissa                  25 Boone, will now swear in the witness.</p>	<p style="text-align: right;">Page 9</p> <p>1 action and the general causation, so there were                  2 some elements that are similar in both.                  3 Q. And is this meant to supercede                  4 your general causation expert report?                  5 MR. FOWLER: Objection, form.                  6 THE WITNESS: Not to supercede.                  7 As -- as part of my academic career,                  8 whenever there's a -- a literature                  9 search and evaluation, a -- a process                  10 that you go through, you review and add                  11 information to what you already know.                  12 So it's not meant to replace previous                  13 information, if that's what the question                  14 was.                  15 BY MR. VAUGHN:                  16 Q. And so what content did you add                  17 to this expert report?                  18 A. I think the biggest addition is                  19 the bioequivalence description assessment and                  20 analysis and a section on the process of                  21 pharmacokinetic accumulation. And then a -- a                  22 third area was a -- a section where I comment on                  23 the -- the need for medical monitoring.                  24 Q. And you said that the purpose of                  25 this was not to replace previous information.</p>

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<p>1 Were there changes actually made, though, to your 2 general causation opinions in here? 3 MR. FOWLER: Objection, form. 4 THE WITNESS: I don't recall 5 making any changes to my previous report 6 in this report. 7 MR. VAUGHN: Melisha, can we go 8 ahead and pull up the class action 9 expert report he submitted? 10 And that will be Exhibit 1. 11 (Exhibit 1 was marked.) 12 BY MR. VAUGHN: 13 Q. And, Mr. Bottorff, is this 14 your -- the expert report you submitted for the 15 class action in this litigation? 16 A. Yes, it is. 17 MR. VAUGHN: And, Melisha, can we 18 split-screen that with his general 19 causation report? 20 And let's mark that as Exhibit 2. 21 (Exhibit 2 was marked.) 22 BY MR. VAUGHN: 23 Q. Now, turning -- 24 MR. VAUGHN: On the class action 25 expert report, can we please go to page</p>	<p>1 highlighting in blue. Or now yellow. 2 BY MR. VAUGHN: 3 Q. Do you have your class action 4 expert report with you? 5 A. Yes. 6 Q. Can you find anywhere in your 7 class action expert report where -- where it still 8 discusses ZHP's internal nitrosamine testing on 9 their API? 10 A. Yeah, I don't -- I don't see it. 11 Q. Are you the one that removed that 12 from your expert report? 13 A. I probably was, since I wrote 14 this myself. 15 Q. Why did you remove that from your 16 expert report? 17 MR. FOWLER: Objection to form, 18 "remove." 19 Go ahead, Doctor. 20 THE WITNESS: I can't tell you 21 right now why I did not include the same 22 wording. The -- the following 23 information, which is the -- the FDA 24 values, I believe they are identical. 25 BY MR. VAUGHN:</p>
Page 11	Page 13
<p>1 7, Melisha? And on the general 2 causation report, can we go to page 6. 3 BY MR. VAUGHN: 4 Q. Okay. So on the right-hand side, 5 you see on your general causation report, 6 you -- line 114, that entire paragraph, you note: 7 "When ZHP became aware of the nitrosamine 8 impurities, ZHP tested certain of its inactive 9 ingredient -- active pharmaceutical ingredient 10 batches and determined that the levels of NDMA 11 range from 3.4 parts per million to 120 parts per 12 million"? 13 Do you see that, Dr. Bottorff? 14 A. Yes. Is that what you 15 highlighted in yellow? 16 Q. Correct. 17 And then it -- looking at your 18 class action expert report page 7, line 140, you 19 see that it's now been changed to the FDA testing 20 and any mention of ZHP's testing has been dropped 21 from your expert report? 22 MR. FOWLER: Objection to form, 23 "changed." 24 Go ahead, Doctor. 25 THE WITNESS: I see where you're</p>	<p>1 Q. But ZHP's values are higher than 2 the FDA's values, aren't they? 3 MR. FOWLER: Objection. 4 THE WITNESS: If I went back and 5 calculated. (Technical interference) 6 probably do that. But I think -- 7 BY MR. VAUGHN: 8 Q. But -- 9 A. -- they are higher. 10 MR. VAUGHN: All right. Melisha, 11 can we go to page 22 on the class action 12 report now? And let's compare that to 13 page 21 of the general causation report. 14 All right. And I'm looking at 15 line 364 where it says: "Presence of 16 trace amounts of NDMA/NDEA on the 17 general causation report," Melisha. The 18 one on the right. Line 364. Yeah. 19 BY MR. VAUGHN: 20 Q. And then -- you see that, Doctor, 21 line 364, where you note the -- the amounts being 22 trace amounts? 23 A. Yes. 24 Q. Okay. And can we compare that, 25 then, to your class action expert report on page</p>

<p style="text-align: right;">Page 14</p> <p>1 22, line 374? It now says: "Presence of NDMA and                  2 NDEA," the words "trace amounts" have been dropped                  3 from your expert report, correct?                  4 A. They're not there.                  5 Q. Are you the one that removed                  6 those words?                  7 A. I wrote this, so I must have.                  8 Q. Why did you remove those words                  9 from your expert report?                  10 A. I have no particular reason.                  11 MR. VAUGHN: All right. Melisha,                  12 let's go to page 45 of this class action                  13 expert report. And let's compare that                  14 to page 25 of his general causation                  15 expert report.                  16 BY MR. VAUGHN:                  17 Q. In the general causation expert                  18 report on that line 439, the sentence that reads:                  19 "The concern over the detection of these                  20 impurities is that the international agency for                  21 research on cancer, IARC, has categorized                  22 nitrosamines as a probable human carcinogen based                  23 on annual studies primarily involving rats."                  24 Do you see that in your general                  25 causation report, Mr. Bottorff?</p>	<p style="text-align: right;">Page 16</p> <p>1 MR. VAUGHN: Let's go to page 47                  2 of his class action report, and let's                  3 compare that to page 27 of his general                  4 causation expert report.                  5 BY MR. VAUGHN:                  6 Q. And on your general causation                  7 expert report, I'm looking at the lines 473 and                  8 474. So it ends with: "The carcinogens produced"                  9 at 473.                  10 Do you see where I'm looking at,                  11 Mr. Bottorff?                  12 A. Yes.                  13 Q. And so now if you look at the                  14 class action expert report Line No. 749, you've                  15 now inserted a heading "NDE" -- "NDMA and NDEA and                  16 valsartan will not reach systemic circulation."                  17 Do you see that, Dr. Bottorff?                  18 A. I do.                  19 Q. Why was that added to your expert                  20 report?                  21 MR. FOWLER: Objection to form,                  22 "added."                  23 THE WITNESS: I guess I was                  24 trying to -- doing what I would call                  25 sort of format form, outline form, sort</p>
<p style="text-align: right;">Page 15</p> <p>1 A. I do.                  2 Q. Okay. Now looking at your class                  3 action expert report line 724, that entire                  4 sentence is no longer in your expert report, is                  5 it?                  6 A. No.                  7 Q. And did you remove that language                  8 from your expert report as well?                  9 A. It's not there, so it got                  10 removed. But it wasn't removed for any particular                  11 reason that I can give you.                  12 Q. And you're the one that removed                  13 that language?                  14 A. I wrote this, so it would have                  15 been me.                  16 Q. And there's no particular reason                  17 you removed the language about nitrosamines being                  18 probable human carcinogens?                  19 MR. FOWLER: Objection, form.                  20 Other than the scope of the                  21 report?                  22 THE WITNESS: And so, no,                  23 I -- I'm -- I'm the one, if it came out,                  24 that took it out. And there was no                  25 particular reason for that.</p>	<p style="text-align: right;">Page 17</p> <p>1 of identify areas in this second report                  2 that I would have sections on. So it                  3 was a -- working from an outline to the                  4 report.                  5 BY MR. VAUGHN:                  6 Q. And does NDMA or NDEA reaching                  7 systemic circulation have anything to do with                  8 bioequivalency studies?                  9 A. The presence of NDMA and NDEA in                  10 valsartan, are you asking if that would have an                  11 effect on valsartan's bioequivalence?                  12 Q. Correct. Does NDMA or NDEA being                  13 in valsartan and the NDMA or NDEA reaching                  14 systemic circulation, does that have any impact on                  15 valsartan bioequivalency studies?                  16 MR. FOWLER: Objection: Form,                  17 compound.                  18 THE WITNESS: First, I'm -- I'm                  19 trying to speak real loud to make sure                  20 that you can hear. So if it seems like                  21 I'm yelling, it's not in an -- an                  22 aggressive kind of response.                  23 BY MR. VAUGHN:                  24 Q. I appreciate it and your -- your                  25 level is actually pretty good.</p>



<p style="text-align: right;">Page 18</p> <p>1 A. Okay. I -- I just didn't want it                  2 to come across as -- but I wanted to be sure I got                  3 heard.                  4 No, I do not believe that the                  5 presence of NDMA or NDEA in valsartan has anything                  6 to do with valsartan's bioequivalence.                  7 Q. And it reaching systemic                  8 circulation -- scratch that.                  9 And NDMA or NDEA reaching                  10 systemic circulation has nothing to do with the                  11 bioequivalency studies for valsartan, correct?                  12 MR. FOWLER: Objection: Form,                  13 lack of foundation, facts not in                  14 evidence.                  15 THE WITNESS: Because I conclude                  16 that they would not reach the systemic                  17 circulation, then, again, my best answer                  18 to your question is that they have no                  19 effect on valsartan's bioequivalence.                  20 BY MR. VAUGHN:                  21 Q. The opinion that NDMA and NDEA in                  22 valsartan will not reach systemic circulation is                  23 in relation to your general causation opinions,                  24 correct?                  25 MR. FOWLER: Objection: Form,</p>	<p style="text-align: right;">Page 20</p> <p>1 almost completely, minimizing exposure to other                  2 tissues and organs."                  3 Do you see that in your prior                  4 report, Dr. Bottorff?                  5 A. I do.                  6 Q. All right. And let's compare                  7 that to the sentence that starts on lines 761 of                  8 your class action expert report that reads: "Oral                  9 doses at the levels detected in generic valsartan                  10 at issue in this litigation are metabolized in the                  11 liver almost completely, preventing exposure to                  12 other tissues and organs."                  13 Did I read that correctly,                  14 Dr. Bottorff?                  15 A. Yes.                  16 Q. What changes did you make in that                  17 sentence from your general causation expert report                  18 to your class action expert report?                  19 A. I don't feel that I made any                  20 substantial changes at all.                  21 Q. Okay. Do you see in the general                  22 causation report you used the word "minimizing                  23 exposure to other tissues and organs"? The word                  24 "minimizing"?                  25 A. Yes.</p>
<p style="text-align: right;">Page 19</p> <p>1 mischaracterizes.                  2 THE WITNESS: I think it's, as I                  3 said earlier, that there is some overlap                  4 in some of the issues between general                  5 causation and this part of the                  6 litigation, as I understood it, and the                  7 concept of -- of first pass metabolism                  8 is one of those areas of overlap between                  9 the two reports.                  10 BY MR. VAUGHN:                  11 Q. How does first pass metabolism of                  12 NDMA or NDEA impact the bioequivalency studies of                  13 valsartan?                  14 A. It does not.                  15 MR. VAUGHN: Melisha, let's go to                  16 page 48 of his class action expert                  17 report. Let's compare that to page 28                  18 of his general causation expert report.                  19 Looking at line 486 of his general                  20 causation report where it says:                  21 "Minimizing exposure to other tissues                  22 and organs..."                  23 BY MR. VAUGHN:                  24 Q. And the full sentence reads:                  25 "Smaller oral doses are metabolized in the liver</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. And do you see that that's been                  2 changed to the word "preventing"? It now says:                  3 "...preventing exposure to other tissues and                  4 organs."                  5 Do you see that?                  6 A. I do.                  7 Q. Do you not think there's much of                  8 a difference between "minimizing" and                  9 "preventing"?                  10 MR. FOWLER: Objection,                  11 argumentative.                  12 THE WITNESS: Conceptually, what                  13 those two sentence [sic] were -- I think                  14 mean the same thing about -- because of                  15 first pass metabolism, that you minimize                  16 exposure, you prevent exposure, you                  17 minimize/eliminate risk, and I think                  18 they're -- they're just a reflection of                  19 the fact that I did not just simply cut                  20 and paste from my previous report                  21 into -- into this report. I -- I sat                  22 down and wrote it de novo with the same                  23 knowledge base and information.                  24 BY MR. VAUGHN:                  25 Q. And this sentence that you</p>

<p style="text-align: right;">Page 22</p> <p>1 changed has nothing to do with the bioequivalency                  2 studies, correct?                  3 A. Correct.                  4 MR. VAUGHN: Let's go to page 52                  5 of his class action expert report,                  6 Melisha. And let's compare that to page                  7 62 of his general causation expert                  8 report.                  9 BY MR. VAUGHN:                  10 Q. All right. In looking at the                  11 class action expert report, line 830, do you see                  12 where you note that: "DNA repair mechanisms in                  13 humans can be as much as ten times higher than                  14 rats"?                  15 A. Yes.                  16 Q. Okay. And looking at your                  17 general causation expert report, do you see that                  18 language anywhere?                  19 A. Not in the page that -- that you                  20 have in front of me.                  21 Q. Do -- do you have your general                  22 causation expert report?                  23 A. I can probably get a hard copy                  24 because we have a printer here, but I don't have                  25 it sitting right in front of me.</p>	<p style="text-align: right;">Page 24</p> <p>1 there; I just didn't have enough time to find                  2 it -- is I thought I made a statement somewhere in                  3 the report that said that the metabolism of -- of                  4 NDMA in the liver was occurring in the organ that                  5 had the highest capacity to metabolize it.                  6 And that -- that may be in there                  7 somewhere if I go line-by-line and try to find it.                  8 So I may not have quantified it in the original                  9 report, and I quantified it here from a statement                  10 made in -- in one of the PEG articles.                  11 Q. Does quantifying the DNA repair                  12 mechanisms in humans compared to rats have                  13 anything to do with your class action opinions?                  14 A. Yes.                  15 Q. I'm sorry? I didn't hear that                  16 answer.                  17 A. Sorry. Yes.                  18 Q. What does it have to -- what                  19 does -- scratch that.                  20 What do DNA repair mechanisms in                  21 humans have to do with your class action expert                  22 report?                  23 A. The issue of medical monitoring.                  24 Q. And how does that relate to                  25 medical monitoring?</p>
<p style="text-align: right;">Page 23</p> <p>1 Q. Okay. You can also download it                  2 from the exhibit share file, if you would like to.                  3 All right. Dr. Bottorff, if you                  4 could, could you review your general expert report                  5 and see if anywhere in that report you gave the                  6 opinion that DNA repair mechanisms in humans can                  7 be as much as ten times higher than rats?                  8 MR. VAUGHN: And let's go ahead                  9 and go off the record while he's                  10 reviewing this document.                  11 THE VIDEOGRAPHER: The time is                  12 now 9:59 a.m. We are off the record.                  13 (Brief recess observed.)                  14 THE VIDEOGRAPHER: 10:06 a.m.,                  15 we're back on the record.                  16 BY MR. VAUGHN:                  17 Q. All right. Dr. Bottorff, now                  18 that you've had time to review your general                  19 causation expert report, did you find anywhere                  20 within that report that you gave the opinion that                  21 DNA repair mechanisms in humans can be as much as                  22 ten times higher than rats?                  23 A. No, I -- I didn't find it.                  24 And -- and what I was looking for and what I                  25 thought I had in there -- and it may still be in</p>	<p style="text-align: right;">Page 25</p> <p>1 A. Based on first pass metabolism                  2 and limiting exposure of NDMA and NDEA to the                  3 liver, which has the best capability for DNA                  4 repair mechanisms, would mean that there's no                  5 exposure enough to downstream organs to justify                  6 medical monitoring, based on these principles of                  7 both first pass metabolism and DNA repair.                  8 Q. So would it be fair to say that                  9 the DNA repair mechanisms relate to your class                  10 action expert report because you don't believe                  11 that nitrosamines can increase the risk of cancer                  12 in humans?                  13 MR. FOWLER: Objection, form.                  14 THE WITNESS: Yes. And that's                  15 consistent with what I concluded in my                  16 original report, and it's a portion of                  17 what I continue to conclude in this                  18 expert report.                  19 BY MR. VAUGHN:                  20 Q. And so you would agree that's a                  21 general causation expert opinion, the DNA repair                  22 mechanisms in humans?                  23 MR. FOWLER: Objection: Form,                  24 mischaracterizing.                  25 THE WITNESS: I would agree that</p>



<p style="text-align: right;">Page 26</p> <p>1 it has relevance to both the general 2 causation issue in my original report 3 and to the medical monitoring issue that 4 I addressed in this report. 5 BY MR. VAUGHN: 6 Q. And when we went off the record 7 for you to review your general causation expert 8 report and Mr. Fowler went off the screen, did he 9 discuss any part of your testimony with you? 10 A. No. None at all. 11 MR. VAUGHN: All right. Melisha, 12 can we go just to his class action 13 expert report, which is Exhibit 1. And 14 let's go to page 50 and look at line 15 802. 16 BY MR. VAUGHN: 17 Q. Doctor, in this paragraph, you're 18 discussing the half-life of NDMA, correct? 19 A. Correct. 20 Q. And in your opinion, what is the 21 half-life of NDMA in humans? 22 A. It's estimated to be about 13 23 minutes. 24 Q. And what are you basing that 25 estimation on?</p>	<p style="text-align: right;">Page 28</p> <p>1 THE WITNESS: It is as a result 2 of metabolism, and to a certain degree, 3 distribution after IV administration 4 that would result in taking 13 minutes 5 in the estimate in humans, and anywhere 6 between 4 and 26 minutes in other animal 7 species who received IV dosing, for that 8 original concentration to be cut in 9 half, and in that same amount of time, 10 for that concentration to be cut in 11 half. 12 BY MR. VAUGHN: 13 Q. So let me make sure I 14 understand -- 15 A. -- and approximately -- 16 Q. I apologize. 17 A. Sorry, go ahead. 18 Q. I'm sorry if I cut you off -- 19 MR. FOWLER: Let's not -- 20 BY MR. VAUGHN: 21 Q. -- with the delay. 22 MR. FOWLER: -- do that. Yeah. 23 BY MR. VAUGHN: 24 Q. It -- it was not intentional. 25 A. Yeah, so I'll -- I'll finish, and</p>
<p style="text-align: right;">Page 27</p> <p>1 A. I'm using the clearance values 2 from one of the Gombar papers. 3 Q. Did you find the Gombar paper to 4 be reliable? 5 MR. FOWLER: Objection, form. 6 THE WITNESS: In some respects. 7 BY MR. VAUGHN: 8 Q. What is half-life? 9 A. The time it takes for a compound 10 amount to be cut in half. 11 Q. What do you mean "cut in half"? 12 A. Drop by 50 percent. 13 Q. Is that after it's been ingested? 14 A. No. These diag- -- these numbers 15 came from the intravenous data from Gombar, which 16 is the part that I don't have any problem with at 17 all. 18 Q. But the half-life is in relation 19 to the substance being inside the body, correct? 20 A. And in this case, getting there 21 by giving it IV. 22 Q. And so that would mean after 13 23 minutes, if no metabolism is taking place of the 24 NDMA, half of it will have disappeared? 25 MR. FOWLER: Objection, form.</p>	<p style="text-align: right;">Page 29</p> <p>1 then we can take that question. 2 So literally what it amounts to 3 is whatever that original concentration is after 4 you give it intravenously, the half-life -- let's 5 take a round number of ten minutes. It would take 6 ten minutes for that concentration to be cut in 7 half. In ten more minutes, that would be cut in 8 half. And by the time you got to five of those, 9 you can't detect the drug anymore. So a general 10 pharmacology rule is five half-lives and the drug 11 is essentially completely gone. 12 Q. So did I understand you correctly 13 that if NDMA is given intravenously to a human, 14 it's going to take approximately 13 minutes for it 15 to decrease by half? 16 A. An estimate from the Gombar data 17 would predict that, if you were to give it IV. 18 Q. And do you agree with that 19 estimate in Gombar? 20 A. I think it's actually a pretty 21 good estimate. 22 Q. Would it matter how much of a 23 dose is given IV? Will that impact the half-life 24 at all? 25 A. It could.</p>

<p style="text-align: right;">Page 30</p> <p>1 Q. How so?</p> <p>2 A. If -- if a smaller dose is given</p> <p>3 that is in the range of what we call linear</p> <p>4 pharmacokinetics, you'll get a -- a half-life</p> <p>5 value. And if -- if it's a process that can be</p> <p>6 saturated and you give a multiple higher dose,</p> <p>7 then you would saturate elimination and you would</p> <p>8 get a measured longer half-life.</p> <p>9 Q. And in the Gombar study where you</p> <p>10 drew this 13-minute half-life, was it saturated or</p> <p>11 not?</p> <p>12 A. Gombar used his nonsaturated IV</p> <p>13 dose to calculate and then estimate what he</p> <p>14 thought it would be in humans.</p> <p>15 Q. And so in a nonsaturated IV dose</p> <p>16 in humans, NDMA would take 13 minutes to reduce</p> <p>17 the amount in half?</p> <p>18 A. That is an estimate from the</p> <p>19 Gombar data.</p> <p>20 Q. Doctor, do you know how long it</p> <p>21 takes for the blood to do a full circulation in</p> <p>22 the human body?</p> <p>23 A. Off the top of my head, I -- I</p> <p>24 don't. I know I used to know that. And sometimes</p> <p>25 you'll see that expressed as how many cycles per</p>	<p style="text-align: right;">Page 32</p> <p>1 BY MR. VAUGHN:</p> <p>2 Q. If the blood can go all the way</p> <p>3 around the human body multiple times in 13</p> <p>4 minutes, the NDMA would be crossing the liver</p> <p>5 multiple times, wouldn't it?</p> <p>6 MR. FOWLER: Objection: Form,</p> <p>7 lack of foundation, facts not in</p> <p>8 evidence, incomplete hypothetical.</p> <p>9 THE WITNESS: The -- the best</p> <p>10 answer I can give you in a conceptual is</p> <p>11 that when a drug is given IV, whether</p> <p>12 it's NDMA or, you know, a -- an</p> <p>13 FDA-approved drug, giving it in the IV</p> <p>14 route, it does eventually, if it is</p> <p>15 metabolized in the liver, pass through</p> <p>16 the liver as part of its route of</p> <p>17 elimination.</p> <p>18 BY MR. VAUGHN:</p> <p>19 Q. If the liver is able to fully</p> <p>20 metabolize NDMA and systemic circulation takes</p> <p>21 less than five minutes, you wouldn't expect the</p> <p>22 half-life to be 13 minutes, would you?</p> <p>23 A. The issue that I have in being</p> <p>24 able to answer it to the best of my ability is</p> <p>25 that I'm not sure the first part of the question</p>
<p style="text-align: right;">Page 31</p> <p>1 day or how man- -- how long it takes for one</p> <p>2 cycle. So I know that's available information,</p> <p>3 but I don't have it off the top of my head.</p> <p>4 Q. Do you have an estimate, even?</p> <p>5 A. I know blood volume is</p> <p>6 approximately 5 liters. Typical cardiac output is</p> <p>7 about 3 to 4 liters per minute. So it -- it</p> <p>8 shouldn't take long. Less than ten minutes, maybe</p> <p>9 20 minutes. I can't verify that.</p> <p>10 Q. I mean, if -- if cardiac output</p> <p>11 is around 4 liters and blood volume is around 5</p> <p>12 liters, wouldn't you think that it goes all the</p> <p>13 way around the body in about a minute?</p> <p>14 A. Yeah, I don't think that's the</p> <p>15 case, though.</p> <p>16 Q. Okay. You think it might be less</p> <p>17 than 13 minutes, though?</p> <p>18 A. I --</p> <p>19 MR. FOWLER: Objection,</p> <p>20 we're -- we're -- calls for speculation.</p> <p>21 He's answered this.</p> <p>22 THE WITNESS: I really don't</p> <p>23 know. I'd have to look it up, because</p> <p>24 it's been a while since I've had to use</p> <p>25 that information.</p>	<p style="text-align: right;">Page 33</p> <p>1 is accurate. I think I would need to establish</p> <p>2 how long it takes.</p> <p>3 But remember the liver only gets</p> <p>4 part of -- of cardiac output. Part of cardiac</p> <p>5 output goes to other organs as well.</p> <p>6 Q. All right. Sitting here today,</p> <p>7 though, you have no idea how long it actually</p> <p>8 takes for the blood to go around the human body,</p> <p>9 do you?</p> <p>10 A. No. I -- I -- as of right now, I</p> <p>11 don't. I know the value if I were to -- to look</p> <p>12 it up, but I don't have it in front of me.</p> <p>13 Q. And that's not something you've</p> <p>14 looked into in forming your opinions for either of</p> <p>15 your expert reports that you've submitted in this</p> <p>16 litigation, correct?</p> <p>17 A. Correct. And -- and nor do I</p> <p>18 know the relevance that have any impact on my</p> <p>19 opinions anyway.</p> <p>20 MR. VAUGHN: All right. Melisha,</p> <p>21 let's go to his invoices.</p> <p>22 And this will be Exhibit 3. It</p> <p>23 is a composite exhibit of all of the</p> <p>24 invoices that were produced.</p> <p>25 (Exhibit 3 was marked.)</p>

<p style="text-align: right;">Page 34</p> <p>1 MR. VAUGHN: All right. Let's go                  2 to page 3.                  3 BY MR. VAUGHN:                  4 Q. All right. Doctor, and do you                  5 see that you submitted a bill for eight hours of                  6 deposition time on September 1st, 2021?                  7 A. That should probably be November.                  8 So that's a typo.                  9 Q. Why should that be November?                  10 A. Based on the in- -- sorry?                  11 Q. Why should that be November?                  12 A. Oh, no. That -- is that the date                  13 that we did the previous deposition?                  14 Q. Well, we actually did the                  15 previous deposition on September 16th, which you                  16 also billed for.                  17 MR. VAUGHN: Melisha, if you want                  18 to go to page 5 on his invoices.                  19 BY MR. VAUGHN:                  20 Q. Now we have another bill for                  21 \$4,000 for an eight-hour deposition on September                  22 16th, 2021 also in Knoxville and the same start                  23 and end time.                  24 A. Yes. I understand now what                  25 happened. I sent an invoice to GT for the date of</p>	<p style="text-align: right;">Page 36</p> <p>1 September 16th, which was the date of the actual                  2 deposition, you also billed two-and-a-half hours                  3 for reviewing articles in advance of the                  4 deposition. So that's just the morning of the                  5 deposition you're billing?                  6 A. Correct.                  7 Q. Okay. And then the next one on                  8 October 6th, you note that you: "Preview/find                  9 Wang article for inclusion and articles                  10 considered."                  11 What does that mean?                  12 A. That I looked at those articles                  13 to see if I wanted to include them in my articles                  14 for consideration.                  15 Q. That was after you submitted your                  16 expert report and after you sat for deposition,                  17 correct?                  18 A. Correct.                  19 MR. VAUGHN: Let's go to page 7,                  20 Melisha.                  21 BY MR. VAUGHN:                  22 Q. All right, Doctor. Is this where                  23 you started working actually on your class action                  24 expert report?                  25 A. Correct.</p>
<p style="text-align: right;">Page 35</p> <p>1 the deposition, not knowing that that's not who                  2 should have received the invoice. So this invoice                  3 that I sent to GT was never paid.                  4 The other invoice was sent                  5 to -- I don't know which law firm, but they are                  6 the one who eventually paid that invoice. So I                  7 was not paid twice for that deposition.                  8 Q. Why is there a date inaccuracy of                  9 it being September 1st on page 3 of your invoice?                  10 A. Because I'm not very good at                  11 sometimes having the correct date on there.                  12 MR. VAUGHN: All right. Can we                  13 go to the next page, Melisha, page 4.                  14 BY MR. VAUGHN:                  15 Q. And on September 1st, on this                  16 bill, you also billed three-and-a-half hours for                  17 reviewing Lagana's deposition and conference call                  18 with counsel, correct?                  19 A. Correct.                  20 Q. Is that what you actually did                  21 then on September 1st instead of the deposition?                  22 A. Yes, because we just previously                  23 established that that was not the date of the                  24 deposition.                  25 Q. Okay. And then looking at</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. And throughout this I note names                  2 Steve Fowler, Ken -- I'm not even going to try and                  3 pronounce that last name -- T. Harper. Are these                  4 all GT attorneys?                  5 A. Yes.                  6 Q. And is Greenberg Traurig, is that                  7 the law firm you were working with in generating                  8 this class action expert report?                  9 A. Yes.                  10 Q. Is that the only law firm that                  11 you were working with?                  12 A. Yes.                  13 Q. And you were providing opinions                  14 on bioequivalency studies of all of the Defendants                  15 in this litigation, correct?                  16 A. Yes. All that I received                  17 information on.                  18 Q. And GT, Greenberg Traurig, was                  19 the one responsible for giving you documents for                  20 each Defendant?                  21 MR. FOWLER: Objection, form.                  22 THE WITNESS: Yes.                  23 Every -- every document from                  24 manufacturers on ANDAs and                  25 bioequivalence studies that I received,</p>

<p style="text-align: right;">Page 38</p> <p>1 that came through GT. I did not deal                  2 with any of the companies directly.                  3 BY MR. VAUGHN:                  4 Q. Or any of the other law firms?                  5 A. Or any other law firms.                  6 Q. And so if there were additional                  7 documents that you wanted to review, Greenberg                  8 Traurig attorneys would have been who you went to?                  9 A. Yes.                  10 Q. Were there documents that you                  11 specifically asked to see, or is it just documents                  12 that Greenberg Traurig gave you?                  13 A. I asked GT to send me, from as                  14 many of the manufacturers as they could,                  15 bioequivalence studies that were used to file                  16 and -- and received approval for their ANDAs.                  17 And -- and then it was out of my hands what I                  18 received at that point. It was up to the                  19 companies to find and send me those reports                  20 through GT.                  21 Q. And so you would have expected                  22 that all of the bioequivalency studies were given                  23 to you, correct?                  24 A. I don't expect that. I didn't                  25 know what I was going to get. I just evaluated</p>	<p style="text-align: right;">Page 40</p> <p>1 manufacturers, instead of several thousand pages,                  2 I only received the BE data only, and so I didn't                  3 have to sift through for some of the situations a                  4 lot more information than necessary for what I was                  5 doing.                  6 Q. Do you recall for which companies                  7 that was?                  8 A. Not off the top of my head, no.                  9 Q. A second ago you testified that                  10 the submission process is to include the BE data.                  11 By that, do you mean that the company is supposed                  12 to submit all of their bioequivalency data and                  13 studies with their ANDA?                  14 A. I believe that to be the case.                  15 Q. And that's why you thought it was                  16 appropriate just to review the ANDA for their                  17 bioequivalency data, correct?                  18 A. Well, or the bioequivalence data,                  19 if that's all they sent me. I -- it was the                  20 bioequivalence data that I was most interested in.                  21 Q. And when you're talking about the                  22 data, did you actually review the underlying data                  23 or did you just review the final report?                  24 A. It depends on the format that it                  25 came to me. There was often a lot of underlying</p>
<p style="text-align: right;">Page 39</p> <p>1 what I did get.                  2 Q. So I note typically on this you                  3 note that you're reviewing ANDA files for                  4 bioequivalency data. Why is it the ANDA files                  5 that you're reviewing to find the bioequivalency                  6 data?                  7 A. It's -- the part of the ANDA                  8 submission process is to include the -- the BE                  9 data. So I would often get a file that had 50,                  10 60, 70 folders in it, and I had to sift through                  11 those and find the ones that actually had the                  12 bioequivalence data in there.                  13 So there's data on analytical,                  14 the case report forms on all the volunteers who                  15 were in the studies, what their lab values were,                  16 their physical exam results. I mean, there was a                  17 lot of information that's included, and it was                  18 just the BE data that I was interested in sifting                  19 through and finding.                  20 Q. Each of those ANDAs are several                  21 thousands of pages, correct?                  22 A. Correct.                  23 Q. And when you said --                  24 A. Just to add -- I'm sorry. Just                  25 to add and see if it helps. For some of the</p>	<p style="text-align: right;">Page 41</p> <p>1 data. There were bioequivalence data in humans.                  2 A lot of that had subject-by-subject what their                  3 individual values were. Then it had summary data                  4 on top of that. It just depended on the format in                  5 which I received it.                  6 Q. And did you look into the testing                  7 methods that were employed in the different                  8 bioequivalency studies?                  9 A. In some of the more extensive                  10 files that I received, there were testing data.                  11 Q. And -- and for which                  12 manufacturers did you have the more extensive                  13 data?                  14 A. Again, I'd have to go back                  15 and -- and look at my files to make that kind of                  16 accurate answer.                  17 Q. Was it a majority or a minority                  18 of the Defendants that you had extensive data on?                  19 A. I'd say it was about half. So                  20 when you look in my report to see which BE studies                  21 I included, I'd say about half of those came from                  22 looking at a lot of extensive information, and                  23 some were a little bit more targeted towards just                  24 the bioequivalence data.                  25 MR. VAUGHN: Melisha, let's go to</p>

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1 the first page of those invoices again.  
 2 BY MR. VAUGHN:  
 3 Q. And I just want to run through  
 4 the billing amount, total billing amounts, Doctor.  
 5 So this first invoice was  
 6 \$26,000, correct?  
 7 A. Correct.  
 8 MR. VAUGHN: And second invoice,  
 9 Melisha, page 2.  
 10 BY MR. VAUGHN:  
 11 Q. This was \$42,250, correct,  
 12 Doctor?  
 13 A. Correct.  
 14 Q. And the third invoice was \$4,000,  
 15 correct?  
 16 A. Yes, but that may be the one that  
 17 did not get paid because I sent it to the wrong  
 18 firm for payment.  
 19 Q. And do you recall what firm you  
 20 sent that to?  
 21 A. I sent it to GT, and they sent it  
 22 to whatever firm was responsible for that.  
 23 Q. Then the next invoice is \$35,500,  
 24 correct?  
 25 A. Correct.

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1 Q. And the next invoice is \$4,000?  
 2 A. Again, that may be the overlap  
 3 with the other one. So both of those did not get  
 4 paid. One did; one didn't.  
 5 Q. Okay. And the next invoice is  
 6 for \$5,000?  
 7 A. Correct.  
 8 Q. And the next invoice is for  
 9 \$41,000?  
 10 A. Correct.  
 11 Q. And your final invoice is for  
 12 \$46,084, correct?  
 13 A. Correct.  
 14 Q. And my math shows that all those  
 15 together is \$204,000. If we drop that other  
 16 4,000, we're at \$200,000. Does that sound about  
 17 correct to you, Doctor?  
 18 A. That sounds right.  
 19 Q. And have they paid all of those  
 20 invoices to date?  
 21 A. Yes.  
 22 Q. And do you have additional time  
 23 that you have not billed, that is not reflected in  
 24 this billing?  
 25 A. No, I'm sorry. I'm sorry. The

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1 one you're on right now.  
 2 Q. Yeah, the last one?  
 3 A. I have not -- I have not been  
 4 paid for that one.  
 5 Q. Okay. And then do you have  
 6 outstanding time that you have not billed?  
 7 A. Yes. Between the end of last  
 8 week and up until today, I've not billed for that.  
 9 Q. And approximately how much time  
 10 is that?  
 11 A. Approximately, I'm going to say,  
 12 30 hours.  
 13 Q. And what were you doing during  
 14 those 30 hours?  
 15 A. Reviewing my report, reviewing  
 16 deposition transcripts of some of the Plaintiff  
 17 experts in this phase of the litigation,  
 18 rereviewing some of the articles that I thought  
 19 were most important to my conclusions.  
 20 I think that's the majority of  
 21 the work.  
 22 Q. How many meetings have you had  
 23 with counsel in preposit- -- preparation for this  
 24 deposition?  
 25 A. We met yesterday here in Atlanta,

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1 and we had three remote sessions between the end  
 2 of last week and the first part of this week.  
 3 Q. When you say "we," is that all  
 4 Greenberg Traurig attorneys?  
 5 A. Yes.  
 6 Q. Approximately how many hours  
 7 would you say those meetings were in total?  
 8 A. Maybe 16, 18 hours.  
 9 Q. And do you not charge Greenberg  
 10 Traurig more money for when you take a deposition  
 11 versus when you're just writing an expert report?  
 12 A. No, I don't charge differently.  
 13 Q. Let's go ahead and take a five,  
 14 ten-minute break.  
 15 MR. VAUGHN: Is that okay, Steve?  
 16 MR. FOWLER: Five minutes would  
 17 be good. But yeah, go ahead.  
 18 MR. VAUGHN: Sounds great.  
 19 Can we get a breakout room?  
 20 THE VIDEOGRAPHER: Yes.  
 21 The time is now 10:35 a.m. We're  
 22 now off the record.  
 23 (Brief recess observed.)  
 24 THE VIDEOGRAPHER: The time is  
 25 10:43. We're back on the record.



<p style="text-align: right;">Page 46</p> <p>1 MR. VAUGHN: All right, Melisha,                  2 can we go back to Exhibit 1,                  3 Dr. Bottorff's class action expert                  4 report? And let's go to page 30.                  5 BY MR. VAUGHN:                  6 Q. And, Doctor, is this where you                  7 begin discussing these bioequivalency studies of                  8 the various Defendants?                  9 A. Yes.                  10 Q. All right. This first one that                  11 you note is for Teva valsartan, and it's ANDA                  12 090642, correct?                  13 A. Correct.                  14 Q. And those studies, you note, were                  15 conducted in 2004, correct?                  16 A. Correct.                  17 Q. In your opinion, was Teva's                  18 valsartan contaminated with nitrosamines in 2004?                  19 A. I don't believe so, but I don't                  20 know for sure.                  21 Q. Is that something you asked                  22 counsel?                  23 A. No.                  24 Q. Is that something you looked into                  25 in any way at all?</p>	<p style="text-align: right;">Page 48</p> <p>1 MR. FOWLER: Objection to form.                  2 THE WITNESS: Again, I don't know                  3 if it was or wasn't, because                  4 I've -- I've not traced company                  5 documents about that kind of thing.                  6 BY MR. VAUGHN:                  7 Q. Right. I understand that                  8 you're -- you do not know, Dr. Bottorff, but if                  9 it's an "if-then" question. If it was not                  10 contaminated, then this would not tell you                  11 anything about if nitrosamines impact valsartan's                  12 bioequivalency, correct?                  13 A. In and of itself, no.                  14 Q. Going down to line 496, you have                  15 a sentence that reads: "The AUC and Cmax values                  16 are expressed as geometric means rather than the                  17 more common arithmetic means, since the                  18 pharmacokinetic data are usually more log-normal                  19 distributed, such that geometrics means giving                  20 more accurate description of the central tendency                  21 of the data."                  22 Can you explain what that means                  23 to me, Dr. Bottorff?                  24 A. I -- I can as much as neither you                  25 or I are not statisticians. But this is the</p>
<p style="text-align: right;">Page 47</p> <p>1 A. No.                  2 Q. If Teva's valsartan in 2004 was                  3 not contaminated with nitrosamines, how does this                  4 study support that nitrosamines won't impact the                  5 bioequivalency of valsartan?                  6 A. In this particular case, I was                  7 wanting to be thorough and include as many of the                  8 bioequivalence studies as I could get and not                  9 leave those out that -- for whatever reason or any                  10 other reason. So I asked for all of them. And                  11 every one of them that I got, I included in this                  12 report.                  13 Q. In the body of your expert                  14 report, you included every single bioequivalency                  15 study that was provided to you by Greenberg                  16 Traurig?                  17 A. That was provided to them by the                  18 companies who were requested to send it to me,                  19 yes.                  20 Q. And so you would agree, though,                  21 that if, in 2004, Teva's valsartan was not                  22 contaminated with nitrosamines, this                  23 bioequivalency study does not tell you if                  24 nitrosamines will impact the bioequivalency of                  25 valsartan, correct?</p>	<p style="text-align: right;">Page 49</p> <p>1 common way in which all of these bioequivalence                  2 studies are conducted. It's expected in -- from                  3 the FDA when these are submitted that they're                  4 analyzed in that fashion. And it's done for the                  5 reason that I list here, which has to do with how                  6 the data are distributed across normal volunteers.                  7 A lot of statistics are done                  8 assuming that a negative value could be the same                  9 as a positive value, which would lead to that                  10 normal distribution in statistics. But when you                  11 give a drug and measure AUC, it can only go up.                  12 It can't go down. So that's part of this unequal                  13 distribution that leads to this format of                  14 demonstrating the central tendency using the --the                  15 log-normal data.                  16 I can describe how it's done, if                  17 you want to know.                  18 Q. You're not a statistician, are                  19 you, Dr. Bottorff?                  20 A. No, but I've had classes in                  21 statistics and I've actually taught classes in                  22 biostatistics.                  23 Q. What is your prior experience                  24 with bioequivalency studies?                  25 A. My first bioequivalence study</p>



<p style="text-align: right;">Page 50</p> <p>1 experience was when I was a -- a -- a trainee in                  2 my residency at the University of Kentucky, and I                  3 worked in a unit that conducted these kind of                  4 bioequivalence studies. And I've done some of my                  5 own bioavailability studies where the conduct of                  6 the trial is essentially the same.</p> <p>7 Q. What does geometrics mean? What                  8 does that mean?</p> <p>9 A. Yeah. An arithmetic mean is you                  10 take -- let's say we have three numbers, A, B,                  11 and C. You take A plus B plus C, and then you                  12 divide by three and that's the arithmetic means.                  13 The geometrics mean is you multiply A times B                  14 times C, and then you take the cube root of that                  15 number.</p> <p>16 Q. And why does the geometric mean                  17 then give a more accurate description of the                  18 central tendency data?</p> <p>19 A. Well, that's where it gets beyond                  20 my statistical understanding, other than it's                  21 what's expected to be done in these kind of                  22 studies, is they use the geometric instead of the                  23 arithmetic mean.</p> <p>24 Q. Are you familiar with the term                  25 "harmonic mean"?</p>	<p style="text-align: right;">Page 52</p> <p>1 level versus time data that go sort of up and                  2 down, and you try to find the model that draws the                  3 best fit through that data, each data point that's                  4 not on that line -- as there's a difference                  5 between the point and the line that's calculated.                  6 And then the line is refit, the line is refit, and                  7 you take the square of that difference between the                  8 points in the line, and then you select the model                  9 that gives you the least squares difference                  10 between the predicted values and the observed                  11 values.</p> <p>12 Q. Is there a difference between                  13 least square means and geometric least square                  14 means?</p> <p>15 A. No. I think that's a different                  16 way of wording the same process that's done in                  17 bioequivalence studies.</p> <p>18 Q. And what's going to give a more                  19 accurate description of the central tendency of                  20 data, a geometric mean or a geometric least                  21 squares mean?</p> <p>22 A. It's the same thing.</p> <p>23 Q. Oh, those are interchangeable as                  24 well?</p> <p>25 A. Those -- those are</p>
<p style="text-align: right;">Page 51</p> <p>1 A. Yes. There are -- there are                  2 multiple ways of -- of displaying central                  3 tendency. That's another one.</p> <p>4 Q. What is a harmonic mean?</p> <p>5 A. I've never used it, so I can't                  6 define it for you off the top of my head.</p> <p>7 Q. What about a least squares mean?</p> <p>8 A. That's really part of these as                  9 well, is because the FDA expects you, when you do                  10 a comparison from drug A to drug B, to not give                  11 everybody drug A first and drug B second. Some                  12 people will get drug B first and drug A second.                  13 And so you put that into a regression model along                  14 with the means, and the regression model that                  15 gives you the least difference, which is the least                  16 squares fit to the data, are how you determine the                  17 actual values that are going to be reported. So                  18 it's part of the regression model.</p> <p>19 Q. What did you mean by "you put                  20 that into a regression model along with means and                  21 the regression model that gives you the least                  22 difference"? What do you mean by "the model that                  23 gives you the least difference"?</p> <p>24 A. Yeah. The -- the best way I can                  25 describe it is if -- if you have average blood</p>	<p style="text-align: right;">Page 53</p> <p>1 interchangeable.</p> <p>2 Q. Thank you.</p> <p>3 MR. VAUGHN: All right. Let's go                  4 to page 31 of his expert report now.                  5 And looking down at the paragraph that                  6 starts on line 508.</p> <p>7 BY MR. VAUGHN:</p> <p>8 Q. I like that you line number your                  9 expert report, by the way. It makes it much                  10 easier to go through.</p> <p>11 So this is the Princeton ANDA for                  12 the valsartan 320 milligram, ANDA 204821, correct,                  13 Doctor?</p> <p>14 A. Correct.</p> <p>15 Q. And the two studies that were                  16 done here, there was a fasting study, H237-11.                  17 What is a fasting study?</p> <p>18 A. Typically the FDA requires, when                  19 you do these studies, to do one study in -- where                  20 you dose in the morning after an overnight fast so                  21 there's no food in the stomach, and then you                  22 repeat the study with food in the stomach                  23 to -- like after a standard breakfast kind of meal                  24 to see if there's any effect of food altering the                  25 bioavailability or the bioequivalence.</p>

<p style="text-align: right;">Page 54</p> <p>1 Q. And you note that these studies                  2 were done in March and April of 2012. Did you                  3 look into the manufacturing date of the product                  4 that was actually tested in these bioequivalency                  5 studies?                  6 A. I -- I didn't for a -- a point of                  7 record, but most of the files that I received,                  8 there was a section you could go to and it would                  9 talk about the date of actual production of what                  10 was going to be called the test product, and they                  11 even had the date of production of the -- of the                  12 reference Diovan. And they would even often have                  13 what the testing results on those individual                  14 products were.                  15 You know, if it said it had                  16 320 milligrams, did it have 320 or right around                  17 there? So those were often included in the                  18 records that I reviewed.                  19 Q. Do you recall approximately how                  20 much earlier most of the manufacturing dates were                  21 than study dates? Several months?                  22 A. A few months. These are usually                  23 batches that are not so large, because they want                  24 to prove that they can demonstrate bioequivalence                  25 with them before they go into more larger scale</p>	<p style="text-align: right;">Page 56</p> <p>1 studies on bioequivalency don't tell you anything                  2 on if nitrosamines impact valsartan's                  3 bioequivalency, correct?                  4 A. Not by itself.                  5 Q. And what do you mean by "not by                  6 itself"?                  7 A. Well, this report -- and I'm sure                  8 we're going to keep going through it -- is going                  9 to be leading to other bioequivalence studies with                  10 some of the combination products where I                  11 demonstrate that the addition into a valsartan                  12 tablet of milligram quantities of other compounds                  13 that do not have overlapping metabolic or                  14 distribution pathways do not also alter the                  15 bioequivalence. And so to me, it doesn't -- if it                  16 is or isn't in there, it's not going to alter the                  17 bioequivalence pattern.                  18 Q. About line 513, you discuss                  19 Hetero Labs' ANDA 203311 and Studies                  20 10-VIN -- V-I-N -- -337 and Study 330-VALS-2011,                  21 and you note that these studies were conducted in                  22 February and July of 2011, correct?                  23 A. Correct.                  24 Q. And do you know if Hetero Labs'                  25 valsartan was contaminated with nitrosamines in</p>
<p style="text-align: right;">Page 55</p> <p>1 production.                  2 Q. Do any additional tests related                  3 to bioequivalency have to be done when a company                  4 scales up production?                  5 A. I know there are times. The                  6 majority of these, the FDA requires the in-human                  7 bioequivalence study to be done on the largest                  8 tablet size that you're going to market. That's                  9 why these are almost always in the 320 milligram                  10 dosage. And then you're allowed to do in vitro                  11 dissolution testing with the smaller doses.                  12 So even though the bioequivalence                  13 study might have been done with the 320, the ANDA                  14 got approved for 40, 80, 160, as well as the 320.                  15 And that was often done based on dissolution                  16 testing. So when you upscale, you can often                  17 demonstrate bioequivalence using the dissolution                  18 testing rather than repeat your human trial at                  19 that point.                  20 Q. And do you know if Princeton's                  21 valsartan was contaminated prior to March of 2012?                  22 A. I don't specifically know that.                  23 Q. And, again, if Princeton's                  24 valsartan was not contaminated with nitrosamines                  25 at the time of this study, then this -- these</p>	<p style="text-align: right;">Page 57</p> <p>1 2011?                  2 A. Again, I don't. It -- it's my                  3 understanding that some of these generic                  4 manufacturers were making their drug with a                  5 process that may have had nitrosamines in it and                  6 they didn't know it. So I can't tell you with                  7 each company where that was and when that                  8 happened. I -- I'm somewhat certain that some of                  9 these did and it wasn't known, but it still didn't                  10 alter the bioequivalence.                  11 Q. And so is it your testimony today                  12 that Hetero Labs' valsartan might have been                  13 contaminated with nitrosamines dating back to at                  14 least 2011?                  15 A. It is my testimony that I don't                  16 know which companies may have had it, but that I'm                  17 suspicion [sic] -- my suspicion is that some did,                  18 and I don't know which.                  19 Q. All right. Go to page 32, line                  20 517. You are now discussing a Torrent                  21 Pharmaceuticals' ANDA 202728 with Studies                  22 PK-09-100 and Study PK-09-103. These are on                  23 valsartan 320 milligrams, and you note that the                  24 studies were done in July of 2010, correct?                  25 A. Yes.</p>

<p style="text-align: right;">Page 58</p> <p>1 Q. And Torrent's valsartan, is it                  2 your opinion that it was contaminated with                  3 nitrosamines back in 2010?                  4 A. It is my opinion that I don't                  5 know if it was or not.                  6 Q. And if Torrent's valsartan was                  7 not contaminated with nitrosamines back in 2010,                  8 these bioequivalency studies don't tell you                  9 anything in relation to if nitrosamines impact the                  10 bioequivalency of valsartan, correct?                  11 A. And, again, as I said before, not                  12 in and of themselves. But as we keep working                  13 through this, you'll see one of the premises about                  14 having combination products with more than                  15 valsartan, like hydrochlorothiazide in                  16 six-and-a-half -- or six-and-a-quarter up to 25                  17 milligrams, amlodipine 5 or 10 milligrams, having                  18 no effect on the bioequivalence of -- of valsartan                  19 because of a lack of overlapping metabolic                  20 pathways.                  21 And so as I've -- I've                  22 demonstrated in both reports, the lack of an                  23 overlapping metabolic pathway between the                  24 nitrosamines and valsartan, that there would be no                  25 reason, and in fact there couldn't be any reason,</p>	<p style="text-align: right;">Page 60</p> <p>1 limits are to demonstrate that they remained                  2 within the FDA guidelines of the confidence limits                  3 being allowed to be as low as 80 percent or as                  4 high as 125 percent.                  5 Q. So does that mean that --                  6 A. That would be for the A- -- I'm                  7 sorry. Whether that be for the AUC value or the                  8 Cmax value.                  9 Q. And so does that mean that 10                  10 percent of the population is allowed to fall                  11 outside of the 80 percent to 125 percent range?                  12 A. No, that's not what it means.                  13 Q. Can you explain further?                  14 A. Sure. What it means is that if                  15 you were to redo this experiment 100 times, 90                  16 times you would still get values that are between                  17 that range of upper and lower limit. So it's more                  18 of a statistical value than a what-happened-                  19 to-a-patient value.                  20 Q. I understand now. I appreciate                  21 that clarification.                  22 And so on the PK-09-103, it's                  23 getting up to 123.65 percent, and that's okay                  24 because it's less than 125, correct?                  25 A. Correct. That's the upper limit</p>
<p style="text-align: right;">Page 59</p> <p>1 to have that have any effect on the bioequivalence                  2 of valsartan.                  3 Q. What were the two combination                  4 drugs that you just mentioned? Amlodipine and                  5 what was it?                  6 A. Hydrochlorothiazide. Those are                  7 the components of the brand name Exforge or                  8 Exforge HCT.                  9 Q. Are either of those drug                  10 genotoxic -- genotoxins?                  11 A. No.                  12 Q. Are nitrosamines genotoxins?                  13 A. In animals, yes, depending on the                  14 exposure level.                  15 Q. All right. On the PK-09-103                  16 Study, on that far right-hand column, it says:                  17 "90 percent C.I."                  18 What does the C.I. mean?                  19 A. It's a confidence interval. The                  20 90 percent confidence interval around that value                  21 in the column before it, which is the percentage                  22 similarity between the brand name and the test                  23 product. So it's a -- an -- the average value                  24 with the 90 percent confidence limits around that                  25 value. And these are to -- these confidence</p>	<p style="text-align: right;">Page 61</p> <p>1 of the FDA's guidelines for demonstrating                  2 bioequivalence.                  3 MR. VAUGHN: Let's go to page 33,                  4 Melisha.                  5 BY MR. VAUGHN:                  6 Q. All right. Line 537 and 538, you                  7 note that: "HCTZ" -- and what's HCTZ?                  8 A. Hydrochlorothiazide.                  9 Q. Is it okay if I refer to it as                  10 HCTZ in the deposition?                  11 A. For me it is.                  12 Q. Appreciate it.                  13 You note that: "HCTZ is                  14 primarily eliminated through the kidney," correct?                  15 A. Correct.                  16 Q. And then you say: "Therefore,                  17 HCTZ would have no pharmacokinetic or                  18 pharmacodynamic overlap with valsartan or NDMA or                  19 NDEA," correct?                  20 A. Correct.                  21 Q. And why is that?                  22 A. Well, there's multiple parts to                  23 that question. I previously demonstrated how                  24 valsartan is absorbed, taken up into the liver,                  25 excreted in bile and has a mild cytochrome P450</p>

<p style="text-align: right;">Page 62</p> <p>1 pathway of elimination. None of those are shared                  2 by Hydrochlorothiazide. None of those are shared                  3 by NDMA or NDEA.                  4 And I guess I should add that's                  5 the pharmacokinetic reason for no overlap. The                  6 pharmacodynamic reason is that -- that gets to                  7 their mechanism of action. How does                  8 Hydrochlorothiazide lower blood pressure? Not the                  9 same way that valsartan does. So there's no                  10 overlap between their -- their blood pressure                  11 effects. So that would be a lack of a                  12 pharmacodynamic-shared mechanism.                  13 Q. And so is part of the reason that                  14 there's no overlap is they're being metabolized in                  15 different organs?                  16 A. Well, that's part of it. Part of                  17 it can be you're metabolized in the same organ but                  18 by a different pathway. You would still then have                  19 no overlap.                  20 Q. And NDMA is metabolized, in your                  21 opinion, in the liver, correct?                  22 A. And how it's given and how much                  23 dose is -- is given.                  24 Q. The NDMA that has been                  25 contaminated in valsartan, it's your opinion that</p>	<p style="text-align: right;">Page 64</p> <p>1 Q. And is --                  2 A. Different from valsartan,                  3 separate from NDMA.                  4 Q. Thank you. You knew my next                  5 question.                  6 Now, I don't see that you gave an                  7 opinion like you did with HCTZ that it would have                  8 no pharmacokinetic [sic] or pharmacodynamic [sic]                  9 overlap with valsartan or NDMA/NDEA.                  10 Is that also your opinion,                  11 though, with amlodipine?                  12 A. Yes. I -- I say the same thing                  13 in the next sentence, but in a slightly different                  14 way, because there's no identified mechanism of                  15 drug interaction or no overlapping route of                  16 metabolism.                  17 Q. Can liver cirrhosis impact the                  18 metabolism of any of these drugs?                  19 A. Not in a predictable fashion.                  20 Q. What do you mean by that?                  21 A. Well, there are probably maybe as                  22 many as 100 or 150 different cytochrome P450                  23 pathways. Some of them have been studied for                  24 alterations in cirrhosis; some have not. Most do                  25 not show a change in their metabolic capability in</p>
<p style="text-align: right;">Page 63</p> <p>1 it's metabolized in the liver, correct?                  2 A. When ingested orally, yes.                  3 Q. And valsartan itself is also                  4 metabolized in the liver, correct?                  5 A. By a different metabolic pathway                  6 entirely.                  7 Q. And is that the P450 pathway that                  8 you were just mentioning?                  9 A. Well, there's a P450 pathway for                  10 NDMA that's separate and distinct from the minor                  11 P450 pathway with valsartan.                  12 Q. But they're both metabolized                  13 through a P450 pathway, correct?                  14 A. Correct, but a separate and                  15 distinct different P450 pathway.                  16 Q. And then line 545 you note that:                  17 "Amlodipine is primarily hepatically metabolized."                  18 And that means metabolized by the                  19 liver as well, correct?                  20 A. Yes.                  21 Q. And -- I'm --                  22 A. Again, by a distinct metabolic                  23 pathway called 3A4.                  24 Q. P450, 3A4?                  25 A. Yes.</p>	<p style="text-align: right;">Page 65</p> <p>1 cirrhosis.                  2 Q. So liver damage could impact the                  3 metabolism of these drugs?                  4 MR. FOWLER: Object to form.                  5 THE WITNESS: It's probably been                  6 studied and there's other types of liver                  7 damage from cirrhosis, so it can't be                  8 yes/no. You have to look at the type of                  9 liver damage and the specific P450                  10 pathway to see what's actually been                  11 demonstrated or shown not to have an                  12 effect. But it can't be done as a                  13 blanket statement.                  14 BY MR. VAUGHN:                  15 Q. Do you have an opinion as to what                  16 type of liver damage would impact the metabolism                  17 of any of these drugs the most?                  18 MR. FOWLER: Objection: Form,                  19 foundation.                  20 THE WITNESS: I don't. As I said                  21 before, it's not something you can say                  22 in a blanket yes/no format. So you'd                  23 have to literally look at each pathway                  24 and the multiple different types of                  25 hepatic disease to see what's been done</p>

<p style="text-align: right;">Page 66</p> <p>1 and what's not been done.</p> <p>2 MR. VAUGHN: Let's go to page 34,</p> <p>3 Melisha.</p> <p>4 BY MR. VAUGHN:</p> <p>5 Q. And at 559, we're now at the</p> <p>6 section on Exforge. What is Exforge?</p> <p>7 A. That's the brand name of the</p> <p>8 combination product of valsartan and amlodipine</p> <p>9 made by Novartis.</p> <p>10 Q. Okay. So when one of the</p> <p>11 companies is doing their bioequivalency studies on</p> <p>12 valsartan plus amlodipine, they do it in</p> <p>13 comparison to Exforge?</p> <p>14 A. Correct.</p> <p>15 Q. And line 562, you are now</p> <p>16 discussing Aurobindo's ANDA 206512, and within</p> <p>17 that, their Study No. 368-12 and 369-12. And you</p> <p>18 note that these were done in October of 2013,</p> <p>19 correct?</p> <p>20 A. Correct.</p> <p>21 Q. And you don't recall the date of</p> <p>22 manufacture of the generic pills that were being</p> <p>23 tested, do you?</p> <p>24 A. No. Again, they would have been</p> <p>25 within some, usually few months time frame, but I</p>	<p style="text-align: right;">Page 68</p> <p>1 A. Again, it -- it can't. There's</p> <p>2 no mechanism for it to do such. This, again,</p> <p>3 study in and of itself is demonstrating that by</p> <p>4 showing that you still get all the valsartan</p> <p>5 you're supposed to get, even when amlodipine is</p> <p>6 present, because it doesn't share a metabolic</p> <p>7 pathway.</p> <p>8 Q. Did you even need to look at any</p> <p>9 of these bioequivalency studies, as you had</p> <p>10 already determined that there's no way that</p> <p>11 nitrosamines can impact the bioequivalency of the</p> <p>12 drugs?</p> <p>13 A. Well, the -- the process that I</p> <p>14 went through was not starting with that. I first</p> <p>15 had to go through the metabolic pathways of these</p> <p>16 various components and then look at the</p> <p>17 bioequivalence studies and then draw my conclusion</p> <p>18 at the end of that, not on the front end of that.</p> <p>19 Q. And you think that studies done</p> <p>20 without nitrosamines can tell you if nitrosamines</p> <p>21 are going to impact the bioequivalency?</p> <p>22 MR. FOWLER: Objection: Form,</p> <p>23 mischaracterizes.</p> <p>24 THE WITNESS: Again, I think in</p> <p>25 answering that previously, I -- I said</p>
<p style="text-align: right;">Page 67</p> <p>1 don't know.</p> <p>2 Q. Okay. So is it your opinion that</p> <p>3 Aurobindo's valsartan was contaminated with</p> <p>4 nitrosamines prior to October of 2013?</p> <p>5 A. It is my testimony that I do not</p> <p>6 know, but that it may have had. And that if it</p> <p>7 did, it didn't alter the bioequivalence anyway.</p> <p>8 Q. And if it -- if that -- scratch</p> <p>9 that.</p> <p>10 And if Aurobindo's valsartan was</p> <p>11 not contaminated with nitrosamines during this</p> <p>12 time, then these bioequivalency studies don't tell</p> <p>13 you anything as to if nitrosamines will impact the</p> <p>14 bioequivalency of valsartan plus amlodipine,</p> <p>15 correct?</p> <p>16 A. Well, no, not necessarily</p> <p>17 correct. Because, again, in microgram quantities,</p> <p>18 without any overlapping mechanism for an</p> <p>19 interaction, there's no reason to expect that</p> <p>20 there would be any impact at all.</p> <p>21 Q. But if this study is testing</p> <p>22 pills without any nitrosamines in it, how does</p> <p>23 that add anything? How does that support your</p> <p>24 opinion that the nitrosamines aren't going to</p> <p>25 impact the bioequivalency?</p>	<p style="text-align: right;">Page 69</p> <p>1 that not in and of themselves. You have</p> <p>2 to look at the whole picture. And part</p> <p>3 of the whole picture is valsartan's</p> <p>4 bioequivalence is retained in the</p> <p>5 presence of other compounds, that I had</p> <p>6 to see the data for, before I could draw</p> <p>7 that conclusion.</p> <p>8 And then also understanding that</p> <p>9 some of these probably had nitrates in</p> <p>10 them, even as far back as -- as when</p> <p>11 these bioequivalence studies were done.</p> <p>12 BY MR. VAUGHN:</p> <p>13 Q. You just testified that you have</p> <p>14 to look at the whole picture. What do you mean by</p> <p>15 "the whole picture"?</p> <p>16 A. Look at all the compounds</p> <p>17 involved, their metabolic pathways, the</p> <p>18 bioequivalence studies.</p> <p>19 Q. All of the bioequivalency</p> <p>20 studies?</p> <p>21 A. All that I received, which</p> <p>22 supported my contention and the -- all of the</p> <p>23 metabolic pathways of all the compounds involved.</p> <p>24 Q. If there were other</p> <p>25 bioequivalency studies that you did not receive,</p>



<p style="text-align: right;">Page 70</p> <p>1 you wouldn't have the whole picture, would you?</p> <p>2 A. I wouldn't have any more</p> <p>3 information than what I've already put in my</p> <p>4 report, but I think there's adequate information</p> <p>5 in my report to make my conclusions.</p> <p>6 Q. If there were bioequivalency</p> <p>7 studies that -- scratch that.</p> <p>8 If some of the generic</p> <p>9 manufacturers conducted bioequivalency studies on</p> <p>10 their valsartan and they failed the bioequivalency</p> <p>11 studies, you would then ex- -- you would have</p> <p>12 expected the Defense attorneys would have given</p> <p>13 you that information, correct?</p> <p>14 A. And they did.</p> <p>15 Q. How do you know they did?</p> <p>16 A. I saw one bioequivalence study</p> <p>17 that the average AUC value and the average Cmax</p> <p>18 value, you know, the two primary determinates of</p> <p>19 rate and extent of absorption, were within the</p> <p>20 FDA's requirements, but the confidence limits</p> <p>21 exceeded the requirements.</p> <p>22 Q. What do you mean by "exceeded"?</p> <p>23 A. So I did see a study --</p> <p>24 Q. Sorry, continue.</p> <p>25 A. So I did see -- I did see a study</p>	<p style="text-align: right;">Page 72</p> <p>1 A. I seem to recall that they were</p> <p>2 using the same API. It was more the tableting</p> <p>3 process that needed to be revised.</p> <p>4 Q. Was it the size of the granules</p> <p>5 of the valsartan API that was causing the</p> <p>6 bioequivalency studies to fail?</p> <p>7 A. No. It was the size of the</p> <p>8 particles that are used as part of the tableting</p> <p>9 process. So, yes, valsartan was in that particle,</p> <p>10 and I don't know whether there was NDMA in there</p> <p>11 or not. But based on the internal report for that</p> <p>12 company, it had nothing to do with the API; it was</p> <p>13 the tableting process.</p> <p>14 Q. What are you basing that on,</p> <p>15 the -- it's the tableting process and not the API?</p> <p>16 A. Their own internal root cause</p> <p>17 analysis.</p> <p>18 Q. But you can't point me to which</p> <p>19 Defendant you're discussing or the document that</p> <p>20 you're relying on?</p> <p>21 A. I could. It might take me two or</p> <p>22 three hours to sift through the files.</p> <p>23 Q. That's okay. I think we'll</p> <p>24 probably get to it later.</p> <p>25 MR. VAUGHN: Let's go to page 36,</p>
<p style="text-align: right;">Page 71</p> <p>1 that failed the FDA's bioequivalence standards and</p> <p>2 the company did a root cause analysis -- I don't</p> <p>3 remember which one it was right now -- and found</p> <p>4 that it was a -- a change in the size of the</p> <p>5 microparticles when they did the tableting, and so</p> <p>6 they went back and reformulated the tablet and</p> <p>7 redid a bioequivalence study -- and its one of the</p> <p>8 ones that's in here -- that then met the FDA</p> <p>9 standards after the reformulation.</p> <p>10 Q. You don't recall what company</p> <p>11 that is?</p> <p>12 A. I don't. I'd have to go back and</p> <p>13 look through all those files again.</p> <p>14 Q. Do you know what -- if they're</p> <p>15 API?</p> <p>16 A. Again, I -- I don't know off the</p> <p>17 top of my head whether they made their own or</p> <p>18 whether they purchased it.</p> <p>19 Q. You don't know if they were</p> <p>20 getting their API from ZHP?</p> <p>21 A. I don't, off the top of my head.</p> <p>22 Q. And do you happen to know if</p> <p>23 wherever they were getting their API from sent</p> <p>24 them the same API later on that they passed their</p> <p>25 bioequivalency study with?</p>	<p style="text-align: right;">Page 73</p> <p>1 Melisha, and start on line 586.</p> <p>2 BY MR. VAUGHN:</p> <p>3 Q. All right. We're talking about</p> <p>4 Torrent's ANDA 202377. And so this would, again,</p> <p>5 be the valsartan plus amlodipine, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And the bioequivalency studies</p> <p>8 within this ANDA is PK-09-192, PK-09-193 and</p> <p>9 PK-10-023, and you note that these were conducted</p> <p>10 between May and July of 2010, correct?</p> <p>11 A. Yes.</p> <p>12 Q. Is it your opinion that Torrent's</p> <p>13 valsartan was contaminated with nitrosamines in</p> <p>14 May of 2010?</p> <p>15 A. Again, it may have been. I -- I</p> <p>16 do not know.</p> <p>17 Q. And so, again, if Torrent's</p> <p>18 valsartan was not contaminated with nitrosamines</p> <p>19 in 2010, then these studies don't actually tell</p> <p>20 you anything specifically on if nitrosamines</p> <p>21 impact the bioequivalency of valsartan plus</p> <p>22 amlodipine, correct?</p> <p>23 A. Again, not in and of itself,</p> <p>24 but -- but if it did contain it, then it does tell</p> <p>25 you that.</p>



<p style="text-align: right;">Page 74</p> <p>1 Q. But you have no idea if Torrent's                  2 valsartan was contaminated back in 2010 with                  3 nitrosamines, do you?                  4 MR. FOWLER: Asked and answered.                  5 THE WITNESS: I -- I do not know.                  6 BY MR. VAUGHN:                  7 Q. Do you know what the purpose was                  8 of them doing two fasting studies at different                  9 milligrams?                  10 A. I -- I don't. I don't recall                  11 seeing why that selection was made. Again, I know                  12 they're required by the FDA to do the highest                  13 dose. I don't know why they chose the 160 in                  14 addition, so I -- I really don't know. I                  15 certainly don't recall seeing in the documents I                  16 had access to, that it was explained.                  17 Q. Is there any reason why on the                  18 fed study the bioequivalency range is on the low                  19 end and on the fasting studies it's on the high                  20 end?                  21 MR. FOWLER: Objection to form.                  22 THE WITNESS: I do believe that                  23 it's been reported that there's a small                  24 reduction in systemic exposure to                  25 valsartan when taken with food compared</p>	<p style="text-align: right;">Page 76</p> <p>1 only capable of being different because                  2 of a function of being fed or not.                  3 BY MR. VAUGHN:                  4 Q. Do you -- in relation to                  5 valsartan, do you have an opinion if fasting or                  6 fed bioequivalency studies are harder to pass?                  7 A. I have no opinion that they're                  8 any harder to pass.                  9 MR. VAUGHN: All right. Page 37.                  10 BY MR. VAUGHN:                  11 Q. All right. In the Comparison                  12 part now is Diovan HCT. Is HCT the same as HCTZ?                  13 A. Yes. Novartis, in their branded                  14 name, they don't use all four letters. They just                  15 use three of them. Whereas in the generic                  16 pharmacology vernacular, we always use the four                  17 letters of HCTZ.                  18 Q. Okay. And so this section is now                  19 on the combination of valsartan plus HCTZ pills,                  20 correct?                  21 A. Correct.                  22 Q. And this is Aurobindo ANDA 202519                  23 that you're discussing in this paragraph, correct?                  24 A. Yes.                  25 Q. And the studies within that ANDA</p>
<p style="text-align: right;">Page 75</p> <p>1 to not being taken with food. But then                  2 it's in the package label that                  3 the -- that small reduction is of -- not                  4 of any clinical significance. And so                  5 patients in the package labels are                  6 instructed that they can take it with or                  7 without food and it won't alter the                  8 ultimate response to the drug.                  9 BY MR. VAUGHN:                  10 Q. That small reduction in systemic                  11 exposure to valsartan when taken with food, that                  12 should be the same for the brand name and the                  13 generic, correct?                  14 A. Yes.                  15 Q. Then why is the generic low on                  16 the fed studies but high on the fasting studies?                  17 MR. FOWLER: Objection, form.                  18 THE WITNESS: I don't think it's                  19 only because of whether it's fed or not                  20 fed. I think tablet performance, if you                  21 go back and look through some of these,                  22 some manufacturers, even in a fasting                  23 state, their AUCs are a little higher                  24 than Diovan and some are a little lower                  25 than Diovan. So it -- it's not purely</p>	<p style="text-align: right;">Page 77</p> <p>1 are 304-09 and 305-09. And you note that those                  2 were conducted -- well, actually, you don't know                  3 what year those were conducted, do you?                  4 A. Yeah, I don't know why I didn't                  5 put that in there. I tried to be consistent                  6 in -- in including the actual dates. And so I                  7 don't know if I received only a summary report                  8 that didn't have them.                  9 What I could do, though, is go to                  10 the FDA's website and put in the ANDA number, and                  11 you can get from the website the date that the FDA                  12 approved the ANDA. So I did have that.                  13 Q. Based on Aurobindo's naming                  14 structure of their studies, does that -09 indicate                  15 anything to you?                  16 A. I can't say that I paid attention                  17 to whether that was a 09, like 2009 study or not,                  18 so I don't know for sure. It may have been the                  19 ninth production product or -- you know, I have no                  20 idea.                  21 Q. Or a 2009 manufacturing date of                  22 the product?                  23 A. Could have been.                  24 Q. Well, let's just assume, then,                  25 that this was done in 2010. If this was done in</p>

<p style="text-align: right;">Page 78</p> <p>1 2010, do you have an opinion as to if Aurobindo's                  2 valsartan was contaminated with nitrosamines?                  3 A. I don't know. It may have.                  4 Q. And if the ANDA wasn't approved                  5 until March of 2013, the studies were definitely                  6 done in advance of that, correct?                  7 A. They were definitely done in                  8 advance of 2013, yes. For sure.                  9 Q. And the manufacturing date of the                  10 valsartan would have been even earlier than the                  11 bioequivalency studies, correct?                  12 A. By some, usually, a few months                  13 time frame.                  14 Q. And so you're unaware if the                  15 product tested in these bioequivalency studies was                  16 contaminated with nitrosamines, correct?                  17 MR. FOWLER: Asked and answered.                  18 THE WITNESS: Correct, I'm                  19 unaware of that. They may have been.                  20 BY MR. VAUGHN:                  21 Q. And if Aurobindo's valsartan was                  22 not contaminated with nitrosamines at the time                  23 that these studies were being conducted, these                  24 bioequivalency studies don't actually tell you                  25 anything on if nitrosamines impact the</p>	<p style="text-align: right;">Page 80</p> <p>1 the bioequivalence. And -- and if I recall from                  2 having read one of Plaintiff expert's depositions,                  3 Dr. Najafi, I believe, I think he said the same                  4 thing. It didn't matter whether it was in there                  5 or not; it wouldn't have affected the                  6 bioequivalence.                  7 Q. If there are bioequivalency                  8 studies that were conducted on valsartan that was                  9 known to be contaminated, would you want to review                  10 those studies?                  11 A. Of course if I had them, I would                  12 review them.                  13 Q. Would you give more weight to the                  14 studies that had no nitrosamines impurities in                  15 them versus ones that did have nitrosamines                  16 impurities in them?                  17 A. No, because they're not going to                  18 show any difference, so it wouldn't have any                  19 difference to me at all. Wouldn't change my                  20 conclusion, it would only support my conclusion.                  21 Q. And so without looking at the                  22 studies, you can already determine that they're                  23 not going to show any difference?                  24 A. To the best of our scientific                  25 capability through mechanisms whereby there would</p>
<p style="text-align: right;">Page 79</p> <p>1 bioequivalency of the valsartan plus HCTZ,                  2 correct?                  3 A. And, again -- and the same if                  4 they do.                  5 But without an overlapping                  6 mechanism, it doesn't matter whether it's in there                  7 or not.                  8 Q. And so none of these studies that                  9 we've looked at actually matter to you, do they,                  10 because you don't know if any of them have                  11 nitrosamines in the drug product?                  12 MR. FOWLER: Objection to form.                  13 THE WITNESS: No, that's not what                  14 I said about them not mattering. I'm                  15 saying whether NDMA was in there or not                  16 doesn't matter because the                  17 bioequivalence would be retained.                  18 BY MR. VAUGHN:                  19 Q. So in your expert opinion, it                  20 doesn't matter if the study is using a drug                  21 product with nitrosamines in order to figure out                  22 if nitrosamines impact the bioequivalency of the                  23 drug?                  24 A. It is my expert opinion that                  25 whether they were in there or not would not affect</p>	<p style="text-align: right;">Page 81</p> <p>1 be an effect on bioequivalence, and those                  2 mechanisms do not exist.                  3 MR. VAUGHN: All right. Go on to                  4 page 38.                  5 BY MR. VAUGHN:                  6 Q. All right. And you're now                  7 discussing at line 613 Princeton ANDA 206083. And                  8 again, this is for valsartan plus HCTZ, correct,                  9 Doctor?                  10 A. Yes.                  11 Q. And within the ANDA you note                  12 bioequivalency studies H052-12 and H053-12, and                  13 you note that these were both done in 2012,                  14 correct?                  15 A. Yes.                  16 Q. And do you have any opinion on if                  17 Princeton's valsartan plus HCTZ was                  18 contaminat- -- contaminated with nitrosamines in                  19 2012?                  20 A. I don't personally know that.                  21 They may have been.                  22 Q. And if Princeton's valsartan was                  23 not contaminated with nitrosamines in 2012, these                  24 studies don't actually tell you if nitrosamines                  25 are going to impact the bioequivalency of</p>

<p style="text-align: right;">Page 82</p> <p>1 Princeton's valsartan plus HCTZ, correct?</p> <p>2 A. Correct, in that -- in and of</p> <p>3 itself. But, again, with the presence of</p> <p>4 milligram quantities compared to NDMA microgram</p> <p>5 quantities, without overlapping mechanisms, it</p> <p>6 adds to the body of -- of my knowledge that</p> <p>7 there's no reason to expect that NDMA would have</p> <p>8 any effect on bioequivalence at all.</p> <p>9 Q. Okay. And in the paragraph</p> <p>10 starting at line 622, you are discussing ANDA</p> <p>11 091654, which is for Torrent's valsartan plus</p> <p>12 HCTZ, correct?</p> <p>13 A. Yes.</p> <p>14 Q. And then you note Studies</p> <p>15 PK-09-23 and PK-09-024, and you note that these</p> <p>16 bioequivalency studies were conducted in March of</p> <p>17 2009, correct?</p> <p>18 A. Yes.</p> <p>19 Q. And do you have any opinion if</p> <p>20 Torrent's generic valsartan plus HCTZ was</p> <p>21 contaminated with nitrosamines back in 2009?</p> <p>22 A. I do not know. It may have been.</p> <p>23 Q. And if Torrent's valsartan plus</p> <p>24 HCTZ was not contaminated with nitrosamines back</p> <p>25 in 2009, then these bioequivalency studies don't</p>	<p style="text-align: right;">Page 84</p> <p>1 Here's our bioequivalence result for Diovan/HCT</p> <p>2 versus our equivalent product.</p> <p>3 And so it -- I may have in some</p> <p>4 cases had a much more limited amount of</p> <p>5 information that came with the file that had the</p> <p>6 BE data in it.</p> <p>7 Q. And so for some of the files, you</p> <p>8 were not able to review all the data, correct?</p> <p>9 A. I was able to review the relevant</p> <p>10 bioequivalence data, yes.</p> <p>11 Q. And the Mylan studies, that you</p> <p>12 were discussing in this paragraph, you note were</p> <p>13 conducted in May of 2005, correct?</p> <p>14 A. Yes, I did have that information.</p> <p>15 Q. And did you have any information</p> <p>16 on if Mylan's valsartan plus HCTZ was contaminated</p> <p>17 with nitrosamines back in 2005?</p> <p>18 A. I have no knowledge of that. It</p> <p>19 may have been.</p> <p>20 Q. Your opinion today is that</p> <p>21 Mylan's valsartan might have been contaminated</p> <p>22 going all the way back to 2005?</p> <p>23 A. Do not know.</p> <p>24 Q. And if Mylan's valsartan plus</p> <p>25 HCTZ was not contaminated back in 2005, then these</p>
<p style="text-align: right;">Page 83</p> <p>1 actually tell you anything on if nitrosamines</p> <p>2 impact the bioequivalency of valsartan plus HCTZ,</p> <p>3 correct?</p> <p>4 A. Correct, to a certain degree.</p> <p>5 But, again, without the overlapping mechanisms and</p> <p>6 the fact that it may have had it in there, then</p> <p>7 I -- I don't think this is changing my conclusion</p> <p>8 at all.</p> <p>9 MR. VAUGHN: Page 39.</p> <p>10 BY MR. VAUGHN:</p> <p>11 Q. All right. Paragraph starting</p> <p>12 line 626, you note Mylan data on bioequivalency</p> <p>13 studies comparing generic valsartan/HCTZ to</p> <p>14 Diovan/HCT, but you don't reference an ANDA on</p> <p>15 this one.</p> <p>16 Is there a reason for that?</p> <p>17 A. It was either not identified in</p> <p>18 the files that I received or that I could not find</p> <p>19 it directly at the FDA website to put a specific</p> <p>20 ANDA number in.</p> <p>21 Q. What do you mean by "not</p> <p>22 identified in the files" you received?</p> <p>23 A. As I said before, some of these</p> <p>24 files I received were very lengthy and very</p> <p>25 comprehensive, and some of them I received were:</p>	<p style="text-align: right;">Page 85</p> <p>1 bioequivalency studies don't actually tell you</p> <p>2 anything on if nitrosamines impact the</p> <p>3 bioequivalency of valsartan plus HCTZ, correct?</p> <p>4 A. They indirectly do, as I -- as</p> <p>5 I've stated before, because milligram quantities</p> <p>6 of HCTZ without an overlapping mechanism do not</p> <p>7 alter valsartan. So there would be no reason to</p> <p>8 expect that microgram quantities of NDMA or NDEA,</p> <p>9 without overlapping mechanisms, would have any</p> <p>10 effect on the bioequivalence.</p> <p>11 So I -- I don't change my</p> <p>12 conclusion at all.</p> <p>13 Q. Does that meet FDA guidance, that</p> <p>14 just if there's not a known overlapping mechanism,</p> <p>15 that you don't need to do bioequivalency studies?</p> <p>16 MR. FOWLER: Objection: Form,</p> <p>17 foundation.</p> <p>18 THE WITNESS: The FDA requires</p> <p>19 the bioequivalence studies irrespective</p> <p>20 of whether they do or do not have</p> <p>21 impurities in them.</p> <p>22 BY MR. VAUGHN:</p> <p>23 Q. If a drug has a different</p> <p>24 chemical in it, even if it's an excipient, does</p> <p>25 the FDA require additional bioequivalency studies?</p>

<p style="text-align: right;">Page 86</p> <p>1 MR. FOWLER: Objection, form.                  2 THE WITNESS: Make sure I'm                  3 understanding. Are you asking if two                  4 products have different excipients of                  5 the same active ingredient, would it                  6 require a bioequivalence study?                  7 BY MR. VAUGHN:                  8 Q. Yeah. If a generic drug that                  9 already passed bioequivalency studies added a new                  10 excipient, would the FDA require additional                  11 bioequivalency studies?                  12 A. Probably not in humans. They,                  13 again, would probably be allowed to do a                  14 dissolution study that showed the same release                  15 characteristics.                  16 Q. What are you basing that on?                  17 A. Basing it on the FDA guidance for                  18 bioequivalence testing.                  19 Q. Which FDA guidance on                  20 bioequivalence testing?                  21 A. Probably the one that I referred                  22 to in my report.                  23 Q. Do you know which year that one                  24 is?                  25 A. I don't. I know they released a</p>	<p style="text-align: right;">Page 88</p> <p>1 Q. And their reference drug is,                  2 again, Exforge HCT?                  3 A. Yes. So this is a -- a                  4 three-drug combination now.                  5 Q. Does Exforge HCT have amlodipine                  6 in it?                  7 A. Yes.                  8 Q. And is Exforge HCT what was also                  9 being compared to on the generic valsartan plus                  10 HCTZ but not amlodipine?                  11 A. Valsartan plus amlodipine alone                  12 would be equivalent to the Exforge. Valsartan                  13 plus HCTZ would be equivalent to Diovan/HCT. And                  14 then valsartan plus amlodipine plus                  15 hydrochlorothiazide would be equivalent to the                  16 Exforge HCT.                  17 Q. Understood. Thank you for that                  18 clarification.                  19 And so that last paragraph on                  20 page 39, you are discussing Teva's ANDA 2004354,                  21 valsartan plus amlodipine plus HCTZ, correct?                  22 A. Yes.                  23 Q. And I don't see that you                  24 identified the studies in this ANDA. Do you see                  25 if you did, Doctor?</p>
<p style="text-align: right;">Page 87</p> <p>1 new one maybe last year, but I don't think there                  2 was substantial changes in it.                  3 Q. Did you disagree with anything in                  4 the FDA's guidance?                  5 MR. FOWLER: Objection, form.                  6 THE WITNESS: I'd have to see                  7 what you're referring to.                  8 BY MR. VAUGHN:                  9 Q. As you're sitting here today, do                  10 you recall disagreeing with any of the FDA's                  11 guidance on bioequivalency studies?                  12 A. As I sit here today, I do not                  13 recall that. But I don't know what you're                  14 referring to. It's -- I -- it's so vague, I                  15 can't -- I can't really answer your question.                  16 Q. Are you giving any regulatory                  17 opinions in this litigation?                  18 A. I'm giving no regulatory opinions                  19 in this case. I think there are other people that                  20 have been asked to provide opinions that are much                  21 more qualified than I on that.                  22 Q. At the bottom of page 39, we are                  23 now in the section regarding valsartan plus                  24 amlodipine plus HCTZ, correct?                  25 A. Yes.</p>	<p style="text-align: right;">Page 89</p> <p>1 A. I don't see a specific study                  2 number.                  3 Q. Is there a reason for that?                  4 A. It -- it wouldn't have been an                  5 oversight on my part, so it must not have been                  6 that the actual study number was provided in the                  7 materials I was given to review or that I asked                  8 for to review.                  9 Q. And if the Defendants had that                  10 information, you would have expected that they                  11 would have given it to you, correct?                  12 A. Yes. I'm sure they had it, and                  13 it wasn't in the materials that I received.                  14 Q. You were sure that the Defense                  15 attorneys had it, but they did not give it to you?                  16 MR. FOWLER: Objection, form. He                  17 didn't say that.                  18 THE WITNESS: Yeah, what -- what                  19 I meant to -- to mean is that the file                  20 that came through Defense lawyers to me                  21 from Teva, Teva must not have provided                  22 it in what was sent to them to give to                  23 me. So I had no direct contact with                  24 Teva.                  25 BY MR. VAUGHN:</p>



<p style="text-align: right;">Page 90</p> <p>1 Q. And these studies done in Teva's                  2 ANDA 200435, they were conducted in 2009, correct?                  3 A. Yes, I did have that information.                  4 Q. And do you have an opinion on if                  5 Teva's valsartan was contaminated with                  6 nitrosamines back in 2009?                  7 A. I don't know if it was or not.                  8 Q. And therefore, if it was not                  9 contaminated with nitrosamines back in 2009, these                  10 studies don't tell us anything on if nitrosamines                  11 impact the bioequivalency of Teva's valsartan plus                  12 amlodipine plus HCTZ, correct?                  13 A. Incorrect. Again, this is                  14 an -- an even more extreme example of making my                  15 point. You now have three drugs in milligram                  16 quantities that don't have overlapping mechanisms                  17 of metabolism that show no altered bioequivalence.                  18 Q. And it's your opinion that that                  19 supports that nitrosamines can't alter the                  20 bioequivalency of these drugs?                  21 A. The absence of an overlapping                  22 mechanism of metabolism or distribution,                  23 absolutely, I believe that.                  24 Q. Did you discuss any other                  25 bioequivalency studies in your expert report,</p>	<p style="text-align: right;">Page 92</p> <p>1 I'm even under the impression                  2 that some of the Diovan may have had nitrosamines                  3 in them as well. Again, I don't think it alters                  4 my conclusion at all because it would have no                  5 impact on the bioequivalence studies.                  6 Q. Did the Defense attorneys tell                  7 you to assume that some of the generic valsartan                  8 that was studied in these bioequivalency studies                  9 were contaminated with nitrosamines?                  10 A. Defense attorneys did not tell me                  11 to assume anything. They have access to                  12 information through other depositions and things                  13 that I'm not aware of, but they did tell me that                  14 there was the likelihood that some of these                  15 generics contained NDMA even before ZHP identified                  16 that it had NDMA.                  17 Q. How far back did the Defense                  18 attorneys tell you that the contamination likely                  19 goes?                  20 A. I was not given a time frame. I                  21 do not know that.                  22 Q. And so when you testify --                  23 A. I think it was --                  24 Q. Sorry, go ahead.                  25 A. Yeah. I think I was going to say</p>
<p style="text-align: right;">Page 91</p> <p>1 other than the ones that we have covered?                  2 A. I'm assuming you went through                  3 every one that -- I haven't going back to -- to do                  4 a head count, but I'm assuming it's every one. So                  5 I have no additional ones that I had access to.                  6 Q. And all of the ones that we                  7 reviewed, none of them were you aware if                  8 nitrosamines were in the drug product, correct?                  9 MR. FOWLER: Asked and answered.                  10 THE WITNESS: I don't believe                  11 that I -- I don't know, but I'm under                  12 the impression that some of them did.                  13 BY MR. VAUGHN:                  14 Q. Which ones are you under the                  15 impression had nitrosamines in them when they were                  16 conducting the bioequivalency studies?                  17 MR. FOWLER: Objection, asked and                  18 answered.                  19 THE WITNESS: I -- I don't know                  20 which ones, but I'm under the impression                  21 that some did.                  22 BY MR. VAUGHN:                  23 Q. Do the --                  24 A. I'm even under the                  25 impression -- I'm sorry.</p>	<p style="text-align: right;">Page 93</p> <p>1 that, again, in -- in reading Dr. Najafi's                  2 deposition, I think he was the one that concluded                  3 or -- or stated that even Diovan had some NDMA in                  4 it. And so I'm saying it doesn't matter. The                  5 bioequivalence, and therefore the systemic                  6 exposure, and therefore the systemic effect of                  7 generic valsartan products are completely                  8 independent of whether there is or isn't NDMA in                  9 there or whether it was in the branded products or                  10 not.                  11 Q. Earlier you testified that you                  12 were under the impression they had nitrosamines in                  13 them when they were [sic] conducted the                  14 bioequivalency studies. How are you under that                  15 impression?                  16 MR. FOWLER: Objection: Form,                  17 vague.                  18 THE WITNESS: Again, I'm -- I'm                  19 under the impression from discussions                  20 I've had with counsel that there were                  21 some generic manufacturers that have                  22 identified that they might have had NDMA                  23 even at the time that some of these                  24 bioequivalence studies were conducted.                  25 BY MR. VAUGHN:</p>

<p style="text-align: right;">Page 94</p> <p>1 Q. Did you refute --</p> <p>2 A. And it --</p> <p>3 Q. Sorry.</p> <p>4 A. -- doesn't matter. No. I was</p> <p>5 just going to say it doesn't matter, because it's</p> <p>6 not going to have any effect on the bioequivalence</p> <p>7 anyway.</p> <p>8 Q. Did you review any documents that</p> <p>9 indicated that any of the drug products tested in</p> <p>10 these bioequivalency studies were actually</p> <p>11 contaminated with nitrosamines?</p> <p>12 A. I have -- I have seen no such</p> <p>13 documents, no.</p> <p>14 MR. VAUGHN: Why don't we go off</p> <p>15 the record.</p> <p>16 THE VIDEOGRAPHER: The time is</p> <p>17 now 11:53 a.m. We are off the record.</p> <p>18 (Lunch recess observed.)</p> <p>19 THE VIDEOGRAPHER: The time is</p> <p>20 12:38 p.m. We're back on the record.</p> <p>21 BY MR. VAUGHN:</p> <p>22 Q. Welcome back, Dr. Bottorff.</p> <p>23 MR. VAUGHN: Melisha, can we pull</p> <p>24 up the 2011 FDA Guidance for Submission</p> <p>25 of Summary Bioequivalence Data for</p>	<p style="text-align: right;">Page 96</p> <p>1 a citation down to the Final Rule: "Requirements</p> <p>2 for submission of bioequivalence data that was</p> <p>3 published in the Federal Register on January 16th,</p> <p>4 2009," correct?</p> <p>5 A. Correct.</p> <p>6 Q. And do you agree that an ANDA</p> <p>7 applicant should submit all of their</p> <p>8 bioequivalency studies, even studies which failed?</p> <p>9 MR. FOWLER: Objection: Calling</p> <p>10 for a regulatory opinion, outside the</p> <p>11 scope.</p> <p>12 THE WITNESS: I can sit here and</p> <p>13 read that the same as you can, but,</p> <p>14 again, I -- I don't have opinions</p> <p>15 on -- on regulatory issues.</p> <p>16 BY MR. VAUGHN:</p> <p>17 Q. And so you also don't have an</p> <p>18 opinion on if they're supposed to submit failed</p> <p>19 bioequivalency studies that happened after the</p> <p>20 submission of their ANDA?</p> <p>21 MR. FOWLER: Same objection.</p> <p>22 THE WITNESS: Yeah. Again, I</p> <p>23 have no opinion on that.</p> <p>24 MR. VAUGHN: All right. Melisha,</p> <p>25 let's go to the -- the FDA's 2021 Draft</p>
<p style="text-align: right;">Page 95</p> <p>1 ANDAs?</p> <p>2 And this will be Exhibit 4.</p> <p>3 (Exhibit 4 was marked.)</p> <p>4 BY MR. VAUGHN:</p> <p>5 Q. All right. Have you reviewed</p> <p>6 this document previously, Dr. Bottorff?</p> <p>7 A. Yes, I have.</p> <p>8 MR. VAUGHN: Melisha, can we go</p> <p>9 to PDF page 4? It's page 1 at the</p> <p>10 bottom of the document.</p> <p>11 BY MR. VAUGHN:</p> <p>12 Q. All right. I'm looking at line</p> <p>13 19. Actually, it starts on line 18. Do you see,</p> <p>14 Doctor, where it says: "FDA's final rule on</p> <p>15 requirements for submission of bioequivalence data</p> <p>16 requires an ANDA applicant to submit data from all</p> <p>17 bioequivalence studies the applicant conducts on a</p> <p>18 drug product formulation submitted for approval,</p> <p>19 including studies that do not demonstrate that the</p> <p>20 generic product meets the current bioequivalence</p> <p>21 stamp criteria"?</p> <p>22 A. I see that.</p> <p>23 Q. And at the top of this document,</p> <p>24 it does say that the document contains nonbinding</p> <p>25 recommendations, but the sentence I just read has</p>	<p style="text-align: right;">Page 97</p> <p>1 Guidance now.</p> <p>2 And this will be Exhibit 5.</p> <p>3 (Exhibit 5 was marked.)</p> <p>4 BY MR. VAUGHN:</p> <p>5 Q. Doctor, is this the 2021 Guidance</p> <p>6 that you were referencing earlier in this</p> <p>7 deposition?</p> <p>8 A. Yes. It's the one that I said</p> <p>9 I'd also seen. It existed in a -- in a draft</p> <p>10 format.</p> <p>11 MR. VAUGHN: Go to PDF page 8,</p> <p>12 Melisha. It's going to be page 5 at the</p> <p>13 bottom. And it might be PDF page 9.</p> <p>14 MR. FOWLER: So let me just have</p> <p>15 a running objection to the relevance of</p> <p>16 this 2021 Guidance to this case, so I</p> <p>17 don't interrupt you.</p> <p>18 BY MR. VAUGHN:</p> <p>19 Q. All right. Doctor, on line 147</p> <p>20 where it says: "If a drug product is intended for</p> <p>21 use in both sexes, the applicant should include</p> <p>22 similar proportions of males and females in the</p> <p>23 study or provide a justification supporting the</p> <p>24 use of a single-sex population."</p> <p>25 Why is that?</p>



<p style="text-align: right;">Page 98</p> <p>1 MR. FOWLER: Objection, calls for                  2 a regulatory opinion.                  3 Go ahead, to the extent you can                  4 answer.                  5 THE WITNESS: Yeah, I -- I don't                  6 know why, but I know it's done. On my                  7 CV, I don't know if it was noted or not,                  8 but I've been added to a National                  9 Investigational Review Board for a                  10 company called Advarra. And we review                  11 Phase 1 protocols on a weekly basis from                  12 a variety of pharmaceutical companies,                  13 and I can tell you that the vast                  14 majority of them have about an equal                  15 number of males and females.                  16 Provided, there's all kinds of                  17 stipulations about making sure that it's                  18 females either of nonchild-bearing                  19 potential or who have some of the -- the                  20 highest level of -- of pregnancy                  21 prevention techniques in place.                  22 BY MR. VAUGHN:                  23 Q. And designing a bioequivalency                  24 study like this with -- using both sexes, is that                  25 something that's new as of 2021, or does that date</p>	<p style="text-align: right;">Page 100</p> <p>1 A. I'm not sure. I -- I really                  2 don't know. Maybe to broaden the populations of                  3 people that get exposed to the early phases of                  4 drug development.                  5 Q. In a drug like valsartan, it is                  6 given to both males and females, correct?                  7 A. Well, if the females aren't                  8 pregnant. There's a Black Box Warning: Do not                  9 give it to pregnant females.                  10 Q. And so is that one reason that                  11 you'd want to have both sexes in your studies, is                  12 so you understand how it works in both males and                  13 females?                  14 MR. FOWLER: Form.                  15 THE WITNESS: Again, I don't know                  16 what led to a change, and I don't know                  17 when the change occurred.                  18 BY MR. VAUGHN:                  19 Q. Line 153, it notes: "If a drug                  20 product is prom- -- predominantly intended for the                  21 use in the elderly, the applicant should include                  22 as many subjects as possible at or above age 60."                  23 Do you know why that's                  24 recommended?                  25 A. I'm assuming for what it actually</p>
<p style="text-align: right;">Page 99</p> <p>1 back before 2021?                  2 A. I, again, can't tell you when                  3 that started, but I know it's being practiced as                  4 of today. Since I've been on that IRB, I've seen                  5 numerous trials come through that are practicing                  6 this standard.                  7 Q. And you testified that you've                  8 done bioequivalency studies dating all the way                  9 back to college, correct?                  10 A. Yes.                  11 Q. And in those bioequivalency                  12 studies, was there a fairly equal number of males                  13 and females in the studies?                  14 A. There were not. And that was,                  15 like, 1982-1983. So it was a fair number of years                  16 ago.                  17 Q. And do you have any idea when                  18 that started to change, that they were                  19 recommending to use equal numbers of male and                  20 females in the study?                  21 MR. FOWLER: Asked and answered.                  22 THE WITNESS: I -- I do not.                  23 BY MR. VAUGHN:                  24 Q. And you do not know why that's                  25 recommended?</p>	<p style="text-align: right;">Page 101</p> <p>1 says in that sentence, if it's predominantly                  2 intended to be used in the elderly.                  3 Q. Do elderly metabolize drugs                  4 differently than young people?                  5 A. Again, much like the previous                  6 question about cirrhosis, it's -- it's not a                  7 given. There are many, many studies that I've                  8 seen over the years of my career where the                  9 pharmacokinetics, and therefore the bioequivalence                  10 of a drug, were not altered just by being older.                  11 It's more likely the pharmacodynamics that change,                  12 sensitivity to the heart rate adjustments                  13 or -- it's more the pharmacodynamic end points                  14 that change with -- with aging, not so much the                  15 pharmacokinetic end point. Sometimes. Sometimes                  16 it does. It's not a blanket statement                  17 that -- that fits all.                  18 Q. So it sometimes does.                  19 Would that be a reason you'd want                  20 to actually test it in the population the drug is                  21 being given to?                  22 A. Well, I mean, that's one reason.                  23 Q. Can you give me additional                  24 reasons?                  25 A. Well, maybe, like I said, because</p>

<p style="text-align: right;">Page 102</p> <p>1 they're sensitive, and so you might want to do              2 studies with lower doses, if you didn't do              3 bioequivalence studies with lower doses before.              4 Q. In your opinion, what's the              5 average age of a valsartan user?              6 MR. FOWLER: Objection: Form              7 speculation.              8 THE WITNESS: I -- I could not              9 even come close to what the right answer              10 would be, but I can tell you when you              11 look at the FDA-approved indications for              12 hypertension, heart failure and              13 postmyocardial infarction, those are not              14 going to be 18-year-olds, 20-year-olds,              15 25-year-olds. They're going to be 50-              16 60-, 70-year-olds.              17 BY MR. VAUGHN:              18 Q. And then looking at line 169, it              19 reads: "In such situations, applicant should              20 attempt to enroll patients for whom the drug is              21 intended to treat and whose disease process and              22 treatments are stable for the duration of the              23 study."              24 Do you see that, Doctor?              25 A. Yes.</p>	<p style="text-align: right;">Page 104</p> <p>1 BY MR. VAUGHN:              2 Q. And you see the next line, it              3 says: "Investigational New Drug Application may              4 be required for certain products (such as              5 cytotoxic products.)" And then it cites to 21 CFR              6 312.2(c).              7 Do you see that, Doctor?              8 A. Yes.              9 Q. Were you aware of that?              10 A. Well, I've previously read this,              11 but -- so, yes, I was aware of it.              12 Q. What is an Investigational New              13 Drug Application?              14 A. That's for a drug that's never              15 been given to humans, and so you're looking to get              16 approval to start testing in humans.              17 Q. Is valsartan cytotoxic?              18 A. No.              19 Q. Is NDMA cytotoxic?              20 MR. FOWLER: Form.              21 THE WITNESS: I -- I don't              22 believe so, in what the definition of              23 cytotoxic is, to my recollection. I              24 think of cytotoxic as either antibiotics              25 that are cytotoxic to an organism or</p>
<p style="text-align: right;">Page 103</p> <p>1 Q. Do you agree with that statement?              2 A. Well, not in isolation without              3 the sentence before it. Because in some              4 situations, the drug has a safety consideration              5 that would preclude its use in healthy subjects.              6 So I'm thinking -- what jumps out at me at that              7 point are new cancer drugs.              8 Q. Would --              9 A. You would only want to test those              10 in patients with stable cancer.              11 Q. Thank you for that clarification.              12 Now, when it applies to              13 valsartan, would there be any reason why it should              14 not be tested in the patient population it's              15 intended to treat?              16 MR. FOWLER: Objection: Form,              17 mischaracterizing.              18 THE WITNESS: And I -- I don't              19 think -- again, I think this starts              20 getting into a realm of -- of              21 regulatory, but I don't think the              22 companies who did bioequivalence testing              23 in younger, healthy, normal volunteers              24 was anything other than what the FDA              25 expected to see.</p>	<p style="text-align: right;">Page 105</p> <p>1 cancer drugs that are cytotoxic to              2 cancer cells.              3 BY MR. VAUGHN:              4 Q. What is your definition of              5 cytotoxicity?              6 A. It's a drug that kills cells.              7 And we're talking here about active ingredient, so              8 it's an active ingredient whose intent for use is              9 cytotoxicity.              10 MR. VAUGHN: All right. If we              11 can go to page 22 at the bottom,              12 Melisha. I'm not sure what PDF page it              13 is.              14 BY MR. VAUGHN:              15 Q. All right. I'm looking at the              16 line 846, Handling of Outliers. Doctor, you see              17 this first sentence says: "Applicant should not              18 remove data from the statistical analysis of              19 bioequivalency studies solely because that data              20 are identified as statistical outliers."              21 Do you agree with that statement?              22 A. Well, yes, it's in the FDA              23 document.              24 Q. And you agree that a manufacturer              25 shouldn't remove statistical outliers even before</p>

<p style="text-align: right;">Page 106</p> <p>1 2021, right?</p> <p>2 A. Again, the way in which the data</p> <p>3 are handled can vary. Some of this is relating to</p> <p>4 the fact that some patients or subjects will later</p> <p>5 to [sic] be found to have some reason for it, and</p> <p>6 some of that could be biologic. I mean, I don't</p> <p>7 know the details behind it. Starts getting into a</p> <p>8 statistical handling of the data.</p> <p>9 That's not really what I -- what</p> <p>10 I've done.</p> <p>11 Q. You have not done a statistical</p> <p>12 handling of the data of any of these</p> <p>13 bioequivalency studies?</p> <p>14 A. The kind that are down below in</p> <p>15 870, I have, but not removal of outliers, I've</p> <p>16 not.</p> <p>17 Q. Did you notice in any of the</p> <p>18 bioequivalency studies that you reviewed that the</p> <p>19 manufacturer removed outliers?</p> <p>20 A. Never saw any reference to that</p> <p>21 at all.</p> <p>22 Q. Then going to line 854, it notes</p> <p>23 that: "Data from redosing studies are not</p> <p>24 considered as evidence to support removal of</p> <p>25 outlier data from the statistical analysis. Note</p>	<p style="text-align: right;">Page 108</p> <p>1 what I had in relation to these document requests,</p> <p>2 and I either provided answers or what was</p> <p>3 requested.</p> <p>4 Q. Approximately how many documents</p> <p>5 did you send to GT in relation to this document</p> <p>6 request?</p> <p>7 MR. FOWLER: Objection: Form,</p> <p>8 vague, time frame.</p> <p>9 THE WITNESS: Well, I mean, if</p> <p>10 you want to go through one-by-one....</p> <p>11 But in No. 1, I did not send invoices</p> <p>12 because they had them already.</p> <p>13 BY MR. VAUGHN:</p> <p>14 Q. Oh, Doctor, I just mean in total,</p> <p>15 if that helps you. Just cuts the time up.</p> <p>16 MR. VAUGHN: What's your</p> <p>17 objection?</p> <p>18 MR. FOWLER: You said -- you mean</p> <p>19 in total. You mean a total of documents</p> <p>20 in re- -- sent in response to all 15</p> <p>21 requests? I don't understand --</p> <p>22 MR. VAUGHN: Yeah, that's exactly</p> <p>23 what I'm asking. Yeah. Out of all the</p> <p>24 documents requested --</p> <p>25 MR. FOWLER: As opposed to</p>
<p style="text-align: right;">Page 107</p> <p>1 that all subject data should be submitted and</p> <p>2 potential outliers flagged with appropriate</p> <p>3 documentation as part of the submission."</p> <p>4 And you agree with that as well,</p> <p>5 correct, Doctor?</p> <p>6 A. Yes, it's -- it's in their</p> <p>7 document.</p> <p>8 MR. VAUGHN: Let's pull up the</p> <p>9 depo notice, Melisha.</p> <p>10 It's going to be Exhibit 6.</p> <p>11 (Exhibit 6 was marked.)</p> <p>12 BY MR. VAUGHN:</p> <p>13 Q. Have you seen this document</p> <p>14 before, Dr. Bottorff?</p> <p>15 A. Yes, I have seen it.</p> <p>16 Q. When was this document given to</p> <p>17 you?</p> <p>18 A. I believe it was forwarded the</p> <p>19 day -- well, I don't know in relation to when it</p> <p>20 was received by -- by GT, but I received it in an</p> <p>21 e-mail probably earlier this week.</p> <p>22 Q. And did you help GT in responding</p> <p>23 to this document request?</p> <p>24 A. We went through it line-by-line</p> <p>25 or -- or paragraph-by-paragraph, and I was asked</p>	<p style="text-align: right;">Page 109</p> <p>1 counting?</p> <p>2 MR. VAUGHN: -- in this document,</p> <p>3 I asked him approximately, how many he</p> <p>4 sent to GT.</p> <p>5 THE WITNESS: I'm running down to</p> <p>6 see. I have my recollection in my head,</p> <p>7 but I wanted to look at each of the</p> <p>8 points to make sure that I didn't miss</p> <p>9 something. But the only thing that I</p> <p>10 had that I could give were the notes</p> <p>11 that I was under the impression were</p> <p>12 sent to you.</p> <p>13 I had no PowerPoints. I had no</p> <p>14 tables and charts. I had no books. Any</p> <p>15 of the other things that were requested</p> <p>16 here, I didn't have any- -- anything to</p> <p>17 provide.</p> <p>18 BY MR. VAUGHN:</p> <p>19 Q. Your notes were produced to us.</p> <p>20 I do appreciate you getting those to the Defense</p> <p>21 attorneys. And it was both the notes for the</p> <p>22 general causation expert report you did and the</p> <p>23 class action expert report you did.</p> <p>24 Had you previously given GT's</p> <p>25 Defense attorneys your notes for the general</p>

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1 causation expert report?  
2 A. Yes, I had.  
3 Q. And when was that?  
4 A. I'm assuming in response to the  
5 exact same kind of document prior to the  
6 deposition for -- for the general causation.  
7 MR. FOWLER: They were provided  
8 to you at the time of the general  
9 causation deposition, Mr. Vaughn.  
10 MR. VAUGHN: Did I say they  
11 weren't?  
12 MR. FOWLER: Your question  
13 suggested otherwise, but I just want to  
14 be clear on this record.  
15 BY MR. VAUGHN:  
16 Q. Doctor, are you aware that the  
17 Defense produced 16,632 documents 48 hours ago for  
18 your reliance materials?  
19 A. No. The -- when you combine my  
20 reliance materials from the first phase of  
21 litigation to this phase, there's a lot of -- a  
22 lot of articles that have been looked at and read  
23 and a lot of multipage documents, like the  
24 Guidance for Industry that we looked at a while  
25 ago. So did I do a head count of those? No, I

Page 111

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
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25 [REDACTED]

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1 BY MR. VAUGHN:  
2 Q. And 16,632 sounds kind of  
3 unbelievable, doesn't it?  
4 MR. FOWLER: Form.  
5 THE WITNESS: Not to me, if  
6 that's what's on there. I didn't count  
7 them.  
8 BY MR. VAUGHN:  
9 Q. And so you believe that you've  
10 identified or sent 16,000 documents to the Defense  
11 attorneys?  
12 MR. FOWLER: Mischaracterizing.  
13 THE WITNESS: Again, what got  
14 sent to you, I have a copy of. I  
15 haven't counted the files. I mean, I  
16 don't -- I don't know.  
17 MR. VAUGHN: Melisha, let's pull  
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[REDACTED]

14 BY MR. VAUGHN:

15 Q. Well, setting this document

16 aside, do you agree that an ANDA that includes

17 unreliable data developed at a tainted facility is

18 not and never was substantially complete?

19 MR. FOWLER: Objection. You're

20 calling for a regulatory opinion.

21 You've already asked the doctor if he

22 has those.

23 THE WITNESS: Yeah, that looks

24 like a regulatory thing that I'm not

25 offering opinions on. I don't know what

Page 115

[REDACTED]

Page 117

1 constitutes, in the FDA's mind, a

2 tainted facility and -- and what level

3 of taint they're talking about and what

4 should happen as a result of that.

5 I -- I'm -- I'm not offering any

6 opinions on those.

7 MR. VAUGHN: All right, Melisha

8 let's go to page 3. Two pages later.

9 BY MR. VAUGHN:

[REDACTED]



Page 118

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 BY MR. VAUGHN:  
18 Q. So, Doctor, if a bioequivalency  
19 study is -- if the manufacturer is deleting the  
20 failed test results and retesting the samples  
21 until it achieves the results it sought, would you  
22 consider those bioequivalence studies to be  
23 legitimate?  
24 MR. FOWLER: Objection, form.  
25 THE WITNESS: Again, this

Page 119

1 is -- this is all regulatory. I have no  
2 opinion on the regulatory.  
3 BY MR. VAUGHN:  
4 Q. Did you not evaluate the  
5 legitimacy of the bioequivalency studies that you  
6 opined on?  
7 A. Yes, and they had approved ANDAs.  
8 So they're in a different ball park than what this  
9 is.  
10 Q. Did you evaluate the underlying  
11 studies of the bioequivalency studies to see if  
12 any -- scratch that.  
13 Did you evaluate the underlying  
14 data of the bioequivalency studies to see if  
15 failed testing was deleted and retested until it  
16 got an accurate result and then submitted the  
17 accurate results to the FDA?  
18 A. Again, as I testified this  
19 morning, I only saw one instance of what was a  
20 failed test result, and it was included. My only  
21 exposure to that was what I testified to this  
22 morning.  
23 Q. So you've seen one failed test  
24 result. Have you seen any indication of companies  
25 retesting samples until they get a different

Page 120

1 result?  
2 A. Other than what you just handed  
3 me, no.  
4 Q. And if the companies in this  
5 litigation were doing that with their  
6 bioequivalency studies, would you consider those  
7 studies to be illegitimate?  
8 MR. FOWLER: Objection: Form,  
9 outside the scope.  
10 THE WITNESS: Again, that's a  
11 regulatory, and -- and I have no  
12 evidence that that occurred or didn't  
13 occur, either way.  
14 BY MR. VAUGHN:  
15 Q. Not from a regulatory side, from  
16 a just statistics side from when it comes to a  
17 bioequivalency study and the legitimacy of it. Do  
18 you consider a bioequivalency study legitimate if  
19 they retested the samples until they got the  
20 desired results?  
21 MR. FOWLER: Objection: Form,  
22 scope, incomplete hypothetical.  
23 THE WITNESS: Again, the one  
24 instance that I saw, there was a failed  
25 bioavailability study. They

Page 121

1 reformulated and passed, and I saw both  
2 examples. There was no attempt -- you  
3 know, no sixth time or ten-time attempt  
4 or multiple attempts. It was a one-time  
5 reformulation, and it led to an approved  
6 ANDA.  
7 MR. VAUGHN: Let's go to page 5,  
8 Melisha.  
9 BY MR. VAUGHN:  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]





Page 126

[REDACTED]

Page 128

[REDACTED]

Page 127

[REDACTED]

Page 129

[REDACTED]

14 Q. All right.

[REDACTED]

<div>Page 130</div> <div>[REDACTED]</div>	<div>Page 132</div> <div>[REDACTED]</div>
<div>Page 131</div> <div>[REDACTED]</div>	<div>Page 133</div> <div>[REDACTED]</div>

Page 134

[REDACTED]

Page 136

[REDACTED]

Page 135

[REDACTED]

Page 137

[REDACTED]

<p>Page 138</p> <p>[REDACTED]</p>	<p>Page 140</p> <p>[REDACTED]</p>
<p>Page 139</p> <p>[REDACTED]</p>	<p>Page 141</p> <p>[REDACTED]</p>



Page 144

21

**Q.** Thank you, Doctor.

Page 145

?

Page 146

[REDACTED]

Page 148

[REDACTED]

Page 147

[REDACTED]

Page 149

[REDACTED]

Page 150

[REDACTED]

Page 152

[REDACTED]

Page 151

[REDACTED]

Page 153

[REDACTED]

Page 154

[REDACTED]

Page 156

[REDACTED]

Page 155

[REDACTED]

Page 157

[REDACTED]

23 Q. All right.

[REDACTED]

Page 158

[REDACTED]

Page 160

[REDACTED]

Page 159

[REDACTED]

Page 161

[REDACTED]



Page 162

[REDACTED]

Page 164

[REDACTED]

Page 163

[REDACTED]

Page 165

[REDACTED]

4 MR. VAUGHN: Let's go to RO-MDL-

5 2875-0026534.

[REDACTED]

Page 166

[REDACTED]

Page 168

[REDACTED]

Page 167

[REDACTED]

Page 169

[REDACTED]

Page 170

[REDACTED]

Page 172

[REDACTED]

Page 171

[REDACTED]

Page 173

[REDACTED]

Page 174

[REDACTED]

Page 176

1 This will be Exhibit 19.  
2 (Exhibit 19 was marked.)  
3 MR. VAUGHN: And if we can scroll  
4 down a little bit -- it's about  
5 two-thirds of the way down.  
6 BY MR. VAUGHN:  
7 Q. Doctor, do you see where it says:  
8 The pieces of the company, left after bankruptcy,  
9 did business as PRACS and returned to the name and  
10 the home of one of the legacy companies that had  
11 formed Cetero, C-e-t-e-r-o.  
12 Have you ever heard of Cetero  
13 before?  
14 A. I'm not sure.  
15 Q. If I represent to you that Cetero  
16 is who acquired PRACS, do you have any reason to  
17 disagree with that?  
18 A. No I have no reason to disagree  
19 with that. Like I said, I thought they were  
20 bought out or relocated or something. But that's  
21 about all I knew.  
22 MR. FOWLER: Let me object to  
23 relevance of this document and line of  
24 questioning.  
25 MR. VAUGHN: I'll make it

Page 175

[REDACTED]

Page 177

1 relevant real quick for you.  
2 Let's go to the FD- -- the FDA  
3 letter to Cetero Research, Melisha.  
4 This will be Exhibit 20.  
5 (Exhibit 20 was marked.)  
6 BY MR. VAUGHN:  
7 Q. All right. Doctor, you see this  
8 is a letter from the FDA to Cetero Research?  
9 A. I see that.  
10 MR. FOWLER: I'm going to object  
11 to the document and any hearsay  
12 contained in the document.  
13 BY MR. VAUGHN:  
14 Q. Have you ever seen this document  
15 before, Doctor?  
16 A. No.  
17 Q. All right. That first paragraph  
18 towards the bottom, do you see where it says: FDA  
19 investigators have identified significant  
20 violations of the bioavailability and  
21 bioequivalence requirements of Title 21 Code of  
22 Federal Regulations Part 320?  
23 A. I see that.  
24 Q. Do you see where the FDA goes on  
25 to say that these violations include widespread

<p style="text-align: right;">Page 178</p> <p>1 falsification of dates and times in laboratory                  2 records and subject sample extractions and the                  3 apparent manipulation of equilibrium samples to                  4 meet predetermined accepted criteria?                  5 MR. FOWLER: Objection: Hearsay,                  6 relevance to anything we're talking                  7 about here.                  8 THE WITNESS: Yeah, I see that.                  9 MR. VAUGHN: All right. Let's go                  10 to the next page, Melisha. All right.                  11 Second paragraph, the last sentence.                  12 BY MR. VAUGHN:                  13 Q. Do you see where the FDA says:                  14 "The Complainant was aware that many of the                  15 chemists were manipulating and falsifying data                  16 associated with the samples being used within                  17 various projects"?                  18 MR. FOWLER: Hearsay. A double                  19 layer of hearsay.                  20 THE WITNESS: I see that.                  21 MR. VAUGHN: Let's go to page 5,                  22 Melisha.                  23 BY MR. VAUGHN:                  24 Q. All right. That first paragraph                  25 under No. 2, do you see where they are -- the FDA</p>	<p style="text-align: right;">Page 180</p> <p>1 the bottom.                  2 BY MR. VAUGHN:                  3 Q. Do you see where the FDA says                  4 that this calls into question the validity of all                  5 of the information documented on your AP sheets                  6 including study results that were used as a basis                  7 for NDAs and ANDAs submitted to the FDA?                  8 MR. FOWLER: Form, relevance,                  9 hearsay.                  10 THE WITNESS: I mean, yes, I see                  11 that.                  12 MR. VAUGHN: And let's go to the                  13 next page, Melisha.                  14 BY MR. VAUGHN:                  15 Q. And under the heading                  16 Manipulation of Samples, do you see where it says:                  17 "FDA has determined that your firm manipulated                  18 test samples in order to meet predetermined                  19 acceptance criteria"?                  20 MR. FOWLER: Form, lack of                  21 foundation, facts not in evidence,                  22 relevance.                  23 THE WITNESS: I see that.                  24 MR. VAUGHN: And let's go to                  25 page 10, Melisha.</p>
<p style="text-align: right;">Page 179</p> <p>1 notes that there were frequent alterations in                  2 laboratory records that occurred over a four-year                  3 period from April 1st, 2005 through June 15th,                  4 2009?                  5 MR. FOWLER: Objection: Facts                  6 not in evidence, hearsay.                  7 THE WITNESS: I see it.                  8 BY MR. VAUGHN:                  9 Q. And do you recall the previous                  10 bioequivalency studies that we looked at from                  11 Mylan were within this date range?                  12 A. They were within that date range.                  13 Q. And the company conducting their                  14 bioequivalency studies is the company that the FDA                  15 is saying has frequent alterations in their                  16 laboratory records?                  17 MR. FOWLER: Objection: Form,                  18 hearsay, facts not in evidence.                  19 THE WITNESS: Yeah, I don't see                  20 which studies it applies to, but I see                  21 that.                  22 BY MR. VAUGHN:                  23 Q. All right.                  24 MR. VAUGHN: Let's go down to the                  25 fourth paragraph, three lines up from</p>	<p style="text-align: right;">Page 181</p> <p>1 BY MR. VAUGHN:                  2 Q. And do you see where the FDA, on                  3 the second paragraph, notes they have significant                  4 concerns of all data relevant to FDA-regulated                  5 research?                  6 A. At the Houston facility, yes.                  7 Q. And --                  8 A. My recollection is we talked                  9 about Minneapolis and North Dakota, not Houston.                  10 Q. So it's your opinion that just                  11 the Houston office was manipulating data for this                  12 company?                  13 MR. FOWLER: Objection: Form,                  14 mischaracterizing, lack of foundation,                  15 facts not in evidence.                  16 THE WITNESS: It's not my                  17 testimony. It's what's in the letter                  18 that you just provided me.                  19 MR. VAUGHN: And let's go to                  20 page 11, Melisha.                  21 BY MR. VAUGHN:                  22 Q. And this was signed by the FDA's                  23 Chief of Bioequivalence Investigations branch,                  24 correct?                  25 A. Well, I don't see a signature,</p>



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1 but....

2 Q. The name and the position of the

3 person at the end of the letter is the FDA's Chief

4 of Bioequivalence Investigations branch, correct?

5 MR. FOWLER: Object to the

6 mischaracterization of that being a

7 signature.

8 MR. VAUGHN: Oh, you're right.

9 BY MR. VAUGHN:

10 Q. Signature is the Office of

11 Scientific Investigations and Office of Compliance

12 for the Centers of Drug Evaluation and Research,

13 U.S. FDA, Food & Drug Administration, correct?

14 A. Yes, I see the -- the listing of

15 those people's names and their positions there.

16 MR. VAUGHN: All right, Melisha,

17 let's go to Teva ANDAs Withdrawn over

18 Cetero Data document. Let's go to the

19 second page.

20 This will be Exhibit 21.

21 (Exhibit 21 was marked.)

22 BY MR. VAUGHN:

23 Q. That top paragraph, Doctor, do

24 you see where it says: After a six-year effort,

25 the U.S. FDA has run out of patience with Watson

Page 183

1 Laboratories and InvaGen Pharmaceuticals and is

2 moving to withdraw approval of two of their pr- --

3 abbreviated new drug applications because the

4 firms failed to conduct additional bioequivalency

5 studies for the products the companies' ANDAs were

6 supported by, bioequivalence studies conducted at

7 Cetero Research?

8 MR. FOWLER: Objection: Hearsay,

9 lack of foundation, facts not in

10 evidence, relevance.

11 THE WITNESS: I see that.

12 BY MR. VAUGHN:

13 Q. Are you aware that Watson is now

14 Teva?

15 A. I'm aware that -- now how

16 to -- how to -- how to word who's what, but I

17 think they either bought Watson or incorporated

18 Watson or something.

19 Which -- which ANDAs were

20 withdrawn? Were they the ones I'm talking about

21 or other ANDAs?

22 Q. They're ANDAs that used the same

23 contract research organization to do their

24 bioequivalency studies.

25 A. Well, again, the -- the data that

Page 184

1 you showed me was concerned about the Houston

2 facility. The ANDAs that I cited were done in

3 North Dakota and Minneapolis, No. 1; and then

4 secondly, it looks like the ANDAs that were

5 withdrawn were not the ones that I reported in --

6 in my report.

7 So I think if the FDA had had a

8 problem with those in those other facilities, then

9 they would have withdrawn those like they did

10 these.

11 Q. And you see here it took the FDA

12 six years before they withdrew it, correct?

13 MR. FOWLER: Form.

14 THE WITNESS: I -- I mean,

15 whatever it says, that's what it says,

16 but I'm saying it didn't involve the

17 ANDAs that I reported on.

18 BY MR. VAUGHN:

19 Q. But it did involve the contract

20 research organization that did the studies for the

21 ANDAs you reported on, correct?

22 A. Correct. Except not in the

23 facility that was cited. In the other facilities

24 that was not cited.

25 Q. My headset just made a noise that

Page 185

1 it's low on batteries.

2 MR. VAUGHN: Can we go off the

3 record real quick, just take a

4 five-minute break?

5 THE VIDEOGRAPHER: The time is

6 now 2:45 p.m. We're off the record.

7 (Brief recess observed.)

8 THE VIDEOGRAPHER: The time is

9 2:53 p.m. We're back on the record.

10 MR. VAUGHN: All right, Melisha,

11 can we now pull up

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 [REDACTED]

20 [REDACTED]

21 [REDACTED]

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

Page 186

[REDACTED]

Page 188

1 [REDACTED]

Page 187

[REDACTED]

Page 189

[REDACTED]

Page 190

[REDACTED]

Page 192

[REDACTED]

Page 191

[REDACTED]

14 Q. Okay. All right.

[REDACTED]

Page 193

[REDACTED]

Page 194

[REDACTED]

Page 196

[REDACTED]

Page 195

[REDACTED]

Page 197

[REDACTED]

Page 198

[REDACTED]

Page 200

[REDACTED]

Page 199

[REDACTED]

15 Q. Thank you, Doctor.

[REDACTED]

Page 201

[REDACTED]



25

Page 205

Page 206

[REDACTED]

Page 208

[REDACTED]

Page 207

[REDACTED]

Page 209

[REDACTED]

Page 210

[REDACTED]

Page 212

[REDACTED]

Page 211

[REDACTED]

Page 213

[REDACTED]

Page 214

[REDACTED]

Page 216

[REDACTED]

Page 215

[REDACTED]

Page 217

[REDACTED]

16 MR. VAUGHN: All right, Melisha,  
17 let's go to EMA Press Release regarding  
18 GVK Biosciences.  
19 This will be Exhibit 31.  
20 (Exhibit 31 was marked.)  
21 MR. FOWLER: Let me just lodge an  
22 objection to the EMA exhibit having  
23 nothing to do with products sold in the  
24 U.S.; relevance and hearsay.  
25 Go ahead.

Page 218

1 BY MR. VAUGHN:  
2 Q. Doctor, have you ever seen this  
3 May 22nd, 2015 notice by the EMA?  
4 A. No.  
5 Q. Do you see where the EMA is  
6 suspending medications over flawed studies done by  
7 GVK Biosciences in India?  
8 A. I do see that. I -- I also see  
9 later: "There's no evidence of harm or lack of  
10 effectiveness of any of the medicines linked to  
11 studies conducted by GVK."  
12 Q. Were nitrosamines impurities in  
13 valsartan known in 2015?  
14 A. I don't know.  
15 Q. The third paragraph, do you see  
16 where EMA is discussing that GVK Biosciences  
17 manipulated data regarding generic medications  
18 over a period of the last five years?  
19 MR. FOWLER: Objection to form,  
20 hearsay, lack of foundation, facts not  
21 in evidence.  
22 THE WITNESS: Which page are we  
23 on?  
24 BY MR. VAUGHN:  
25 Q. On the first page, third

Page 219

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]

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1 Q. And GVK Biosciences was doing  
2 those bioequivalency tests for Defendants in this  
3 litigation over the time period referenced in this  
4 letter, correct? Over the last five years, as of  
5 2015, e-mails; so between 2010 and 2015, correct?  
6 MR. FOWLER: Objection: Form,  
7 foundation.  
8 THE WITNESS: Yes. But, again,  
9 you know, they go on to say: "There's  
10 no evidence of harm or lack of  
11 effectiveness, and patients should  
12 continue to take their medicines as  
13 prescribed."  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]

Page 221

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
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18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]

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Page 225

[illegible]



Page 226

[REDACTED]

Page 228

[REDACTED]

Page 227

[REDACTED]

Page 229

[REDACTED]

Page 230

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED]  
8 [REDACTED]  
9 [REDACTED]  
10 [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 MR. VAUGHN: All right. Melisha,  
21 let's pull up Bottorff 0001.  
22 This will be Exhibit 33 [sic].  
23 (Exhibit 34 was marked.)  
24 THE VIDEOGRAPHER: 34, Counsel.  
25 MR. VAUGHN: 34, thank you.

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1 BY MR. VAUGHN:  
2 Q. Doctor, are the -- these the  
3 notes you took in preparation for your general  
4 causation expert report?  
5 A. Yes.  
6 MR. VAUGHN: Melisha, can we go  
7 to 11? All right, C? Do you see where  
8 that's at, Melisha? Yeah, paragraph.  
9 BY MR. VAUGHN:  
10 Q. Doctor, what does the last  
11 sentence of your notes say on that paragraph?  
12 A. "New active ingredient does not  
13 equate to an int- -- contaminant." This is not my  
14 statement. These are -- in this section of my  
15 report, I was making notes on what was in the  
16 original filing. So it's a regurgitation of what  
17 someone else who filed the -- the causation  
18 lawsuit. This isn't me making a statement. It's  
19 me regurgitating what was put by someone else in  
20 the original lawsuit filed.  
21 I even cite page 124, I think, in  
22 that paragraph just above. In the same paragraph,  
23 but just above there. So this isn't me. This is  
24 me quoting what was in the document I reviewed.  
25 Q. Okay. And what about further

Page 232

1 down right below the very bottom where you note:  
2 "FDA inactive ingredients database does not  
3 involve contaminants which are covered under  
4 chemical hazards," is that from a complaint?  
5 A. At this point, to put it into  
6 context, I was talking about the FDA definition of  
7 inactive versus an active ingredient, like I was  
8 referring to a few minutes ago, where the active  
9 ingredient is a drug product intended to furnish a  
10 pharmacologic activity in the diagnosis, cure,  
11 medication, treatment or prevention of disease.  
12 Then there is an inactive  
13 ingredient database. And the FDA's inactive  
14 ingredient database are for things like  
15 excipients, methyl cellulose, mannitol, you know,  
16 things that are used in the tableting process. So  
17 that inactive ingredient database does not include  
18 contaminants. That's under Chemical Hazards in  
19 their database.  
20 Q. And why are you taking notes on  
21 contaminants?  
22 A. Because the section of the report  
23 or the original suit that was filed kept calling  
24 the -- the valsartan products unapproved because  
25 of the president [sic] -- presence of a

Page 233

1 contaminant. So I was making notes about what the  
2 FDA's definitions are in response to that portion  
3 of the filing.  
4 Q. Is NDMA or NDEA chemical hazards?  
5 A. I don't know if they're under the  
6 Chemical Database or not, but they're clearly  
7 considered an impurity.  
8 Q. Are NDMA and NDEA chemicals?  
9 A. Chemicals.  
10 Q. What does the word "hazardous"  
11 mean to you?  
12 A. Causing hazard.  
13 Q. What does "hazard" mean to you?  
14 A. Some form of hazard. It's a very  
15 broad definition.  
16 Q. So it's your position -- go  
17 ahead.  
18 A. I'm sorry. Just in my reports, I  
19 never disagreed with the IARC definition of NDMA,  
20 or NDEA for that matter, being a probable human  
21 carcinogen, which is exactly the category that  
22 they're listed in. I've never disagreed with that  
23 at all. What I've always contended in both  
24 reports, that it's an issue of how much and in  
25 what form of intake.

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1 Q. You don't disagree with the IARC  
2 definition that NDMA or NDEA are probable human  
3 carcinogens, but you dropped it from the second  
4 version of your expert report?  
5 A. I dropped --  
6 Q. Is it --  
7 A. -- saying that I don't believe --  
8 that I don't believe they are able to cause human  
9 carcinogenesis in the route of administration and  
10 at the doses or exposure levels that we're talking  
11 about.  
12 Q. Is it -- in your opinion about  
13 the drugs -- that when drugs are approved but that  
14 they are contaminated -- scratch that.  
15 Is it your position that a drug  
16 is only contaminated when it reaches an unsafe  
17 level of impurity or contaminant?  
18 MR. FOWLER: Objection to form.  
19 You're outside the scope of the class  
20 certification report, Counsel. I'm  
21 letting this go a little bit, but you're  
22 -- you're far afield.  
23 You need the question again,  
24 Doctor?  
25 THE WITNESS: Yeah, if I'm

Page 235

1 expected to answer it, I would like to  
2 hear the question again.  
3 MR. VAUGHN: Court Reporter?  
4 THE COURT REPORTER: Yes?  
5 MR. VAUGHN: I can reask it.  
6 THE COURT REPORTER: It's okay.  
7 I can --  
8 MR. FOWLER: We'll hear -- we'll  
9 hear it from the court reporter, please.  
10 Go ahead.  
11 THE COURT REPORTER: Okay.  
12 (The previous question was read  
13 into the record as follows: "You don't  
14 disagree with the IARC definition that  
15 NDMA or NDEA are probable human  
16 carcinogens, but you dropped it from the  
17 second version of your expert report?")  
18 THE WITNESS: And so, no, there  
19 was no intent by, quote/unquote,  
20 dropping it from my second report, which  
21 was implying that it was done  
22 intentionally, which it was not. So I  
23 still agree with the IARC classification  
24 of being probable human carcinogens. I  
25 have -- I have no reason to disagree

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1 with that.  
2 My point is in humans, I don't  
3 believe they're carcinogenic in the  
4 manner in which they are taken, which is  
5 oral, at the levels of exposure, which  
6 are in the low microgram quantities.  
7 BY MR. VAUGHN:  
8 Q. And is it your position, then,  
9 that the contamination has to reach an unsafe  
10 level before it's actually considered a  
11 contamination?  
12 MR. FOWLER: Objection, beyond  
13 the scope of this report, Counsel.  
14 Can you make any proffer how that  
15 possibly relates to the class  
16 certification report that he has filed,  
17 or am I just missing something?  
18 BY MR. VAUGHN:  
19 Q. Doctor, do you think these drugs  
20 have any value?  
21 A. What I believe, which is in the  
22 -- the rather lengthy Bioequivalence section of my  
23 report, is that the bioequivalence, due to the  
24 presence of NDEA or NDMA, is not altered and,  
25 therefore, they produce the intended therapeutic

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1 benefit, whether it was lowering blood pressure or  
2 managing heart failure or in a post-MI situation.  
3 So, no, I don't believe they had  
4 any loss of their therapeutic benefit.  
5 Q. Are you aware of it being illegal  
6 to sell a drug with an unsafe level of  
7 nitrosamines in them?  
8 MR. FOWLER: Objection to form.  
9 By the very question, it called for a  
10 legal conclusion.  
11 MR. VAUGHN: Please quit  
12 interrupting. You're -- you're coaching  
13 him. You've been coaching him the  
14 entire deposition.  
15 MR. FOWLER: No, I'm not.  
16 MR. VAUGHN: These are improper  
17 depositions. We're going to reserve our  
18 right for sanctions.  
19 MR. FOWLER: So the Court has  
20 asked for specificity in objections,  
21 which I've provided, and it's a proper  
22 objection. Asking him if something is  
23 illegal asks for a legal conclusion.  
24 MR. VAUGHN: Do you not recall  
25 the Court sanctioning you guys because

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1 you were objecting to "the document  
2 speaks for itself" previously, which has  
3 been one of your objections in this  
4 deposition? Do you recall that,  
5 Counselor?  
6 MR. FOWLER: I'm not testifying,  
7 Counsel. Move on.  
8 BY MR. VAUGHN:  
9 Q. Doctor, are you aware that it  
10 would be illegal to sell a drug with unsafe levels  
11 of nitrosamines in them in the United States?  
12 MR. FOWLER: Objection, form.  
13 THE WITNESS: And -- and my  
14 answer is no, I do not have any opinion  
15 on what becomes legal or illegal. I  
16 have no legal opinions in this case.  
17 BY MR. VAUGHN:  
18 Q. If it would be illegal to sell  
19 something in the United States, does it really  
20 have any value?  
21 MR. FOWLER: Form.  
22 THE WITNESS: Again, I have no  
23 opinions on legality. My opinions were  
24 on whether the bioequivalence was  
25 violated by the presence of the

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1 impurities, and I do not believe that  
2 and I believe they maintain their  
3 therapeutic expected response.  
4 BY MR. VAUGHN:  
5 Q. Based purely off of  
6 bioequivalency studies that you reviewed that did  
7 not involve nitrosamines in the drug product?  
8 A. I believe in answering that  
9 question a few times before, I said that there's a  
10 likelihood that some of the products did have  
11 nitrosamine in them. And if they did, it still  
12 wouldn't have affected their bioequivalence, and  
13 therefore their therapeutic response.  
14 Q. And you have no document to cite  
15 to that they were likely contaminated at that  
16 time?  
17 A. I have no document. I've -- I've  
18 previously stated that.  
19 Q. Do you have an understanding of  
20 what it means for a drug to be adulterated?  
21 MR. FOWLER: Objection: Form,  
22 outside the scope of this general --  
23 this class action report.  
24 THE WITNESS: I have a -- a basic  
25 understanding because of my pharmacy

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1 training and background, but my  
2 understanding of adulteration are  
3 impurities that are outside the  
4 manufacturing process, so during storage  
5 or some other nonmanufacturing process  
6 that results in adulteration.  
7 BY MR. VAUGHN:  
8 Q. Transportation of the drug  
9 product count, if it got contaminated during  
10 transportation?  
11 A. I think that probably would fit  
12 under that adulterated category, because it's not  
13 part of the manufacturing process.  
14 Q. And do you know if any of the  
15 Defendants are claiming that their product got  
16 contaminated during transportation?  
17 A. Never seen such materials or  
18 documentation.  
19 Q. Are you aware that if a drug is  
20 contaminated, it's considered adulterated?  
21 MR. FOWLER: You're asking for a  
22 regulatory opinion. It's outside the  
23 scope of this report.  
24 THE WITNESS: Yeah. Again, I --  
25 I don't have regulatory input. That's

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1 -- that's not the nature of my report.  
2 BY MR. VAUGHN:  
3 Q. As a pharmacist, do you have an  
4 understanding that an adulterated drug is not  
5 supposed to be sold to U.S. consumers?  
6 MR. FOWLER: Objection to form.  
7 Again, outside the scope of the class  
8 cert report and opinions therein.  
9 THE WITNESS: Again,  
10 adulteration, I don't know is what we're  
11 talking about here, but pharmacists  
12 would not dispense a known adulterated  
13 product.  
14 BY MR. VAUGHN:  
15 Q. I have no further questions at  
16 this time.  
17 MR. FOWLER: We'll take a few  
18 minutes, and I've got some redirect.  
19 Let's take ten.  
20 THE VIDEOGRAPHER: The time is  
21 now 4:13 p.m. We're off the record.  
22 (Brief recess observed.)  
23 THE VIDEOGRAPHER: The time is  
24 4:26 p.m. We're back on the record.  
25 EXAMINATION

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1 BY MR. FOWLER:  
 2 Q. Dr. Bottorff, I'd like to show  
 3 you what I'm marking as Bottorff Exhibit 35. And  
 4 -- which is Defendants' Responses and Objections  
 5 to Plaintiffs' Notice of Videotaped Oral  
 6 Deposition Michael Bottorff, Pharm.D.  
 7 (Exhibit 35 was marked.)  
 8 BY MR. FOWLER:  
 9 Q. Handing you that. Have you seen  
 10 that document before?  
 11 A. Yes.  
 12 Q. You've reviewed that with us?  
 13 A. I did.  
 14 Q. Okay. Let me mark as Exhibit 36  
 15 your Curriculum Vitae, Doctor.  
 16 (Exhibit 36 was marked.)  
 17 BY MR. FOWLER:  
 18 Q. Can you tell us whether that is  
 19 your -- your current CV?  
 20 A. Yes.  
 21 MR. VAUGHN: Real quick, Counsel.  
 22 Are these in the -- the folder for me to  
 23 access?  
 24 MR. FOWLER: I believe so.  
 25 (Discussion off the record.)

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1 MR. FOWLER: Oh, I see what he's  
 2 doing. Sorry, Counsel. I didn't  
 3 understand my -- my colleague. He's --  
 4 he's load- -- loading those up.  
 5 BY MR. FOWLER:  
 6 Q. Is that -- continuing on 36,  
 7 Doctor.  
 8 Does that CV include your more  
 9 recent appointment to what you referred to as the  
 10 IRB?  
 11 A. Yeah, the Advarra IRB is on here.  
 12 Q. Doctor, you were asked early on  
 13 in the deposition about your experience with  
 14 bioequivalency studies, and I believe you only got  
 15 as far as maybe in your first year of residency at  
 16 the University of Kentucky, or maybe undergrad.  
 17 Have you had other experience  
 18 working with, conducting, bioequivalency studies?  
 19 A. Yeah. When I first started  
 20 faculty at the University of Tennessee, that would  
 21 have been 1983, I was probably involved in and  
 22 analyzed and published maybe a dozen  
 23 pharmacokinetic-based bioavailability studies with  
 24 a variety of cardiovascular drugs. And so those  
 25 are all publications that are -- that are in my

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1 CV. So it went -- it went beyond just me being  
 2 involved in some bioequivalence studies in around  
 3 1982 or 1983, but probably the next ten years, I  
 4 did maybe a dozen more of those kinds of studies.  
 5 Q. Doctor, do you recall some  
 6 questions towards the end of -- of the questioning  
 7 today with -- where you mentioned definitions of  
 8 FDA concerning active ingredients and inactive  
 9 ingredients.  
 10 Do you recall those questions?  
 11 A. I do.  
 12 Q. Let me mark Exhibit 37. This is  
 13 21 CFR 314.3 Definitions.  
 14 (Exhibit 37 was marked.)  
 15 BY MR. FOWLER:  
 16 Q. And if you'd take a look at that,  
 17 Doctor, and I'd ask you: Does that document  
 18 contain FDA's definitions of those active  
 19 ingredient, inactive, things like that?  
 20 A. Yeah. This has -- I mean, it's  
 21 the -- it's the Code of Federal Regulations 314,  
 22 so they're in here.  
 23 Q. Can you locate the Active  
 24 Ingredient definition and read it for the record,  
 25 please?

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1 A. Let's see. "Active ingredient is  
 2 any component that is intended to furnish  
 3 pharmacologic activities or other direct effect of  
 4 the diagnosis, cure, mitigation, treatment, or  
 5 prevention of disease, or to affect the structure  
 6 of function of the body in man or -- or animals,"  
 7 if it's veterinary products.  
 8 "The term includes those  
 9 components that may undergo chemical change in the  
 10 manufacture of the drug product and be present in  
 11 the drug product in a modified form intended to  
 12 furnish the specified activity or effect."  
 13 So it's an intended act or  
 14 ingredient.  
 15 Q. Thank you.  
 16 And can you read Inactive  
 17 Ingredient, please?  
 18 MR. VAUGHN: Steve? Steve, I'm  
 19 still not seeing this document in the  
 20 exhibit folder. I've refreshed it  
 21 several times.  
 22 MR. FOWLER: Tim's working  
 23 vigorously.  
 24 MR. VAUGHN: He's working on  
 25 dropping it in, is that what you said?



<p style="text-align: right;">Page 246</p> <p>1 MR. FOWLER: Yeah. He's working                  2 on it. I threw him a curve ball.                  3 Sorry.                  4 MR. VAUGHN: All right.                  5 MR. FOWLER: He wasn't ready for                  6 that one.                  7 MR. VAUGHN: Not a problem.                  8 BY MR. FOWLER:                  9 Q. Doctor, can you find the                  10 definition of Inactive Ingredient in that CFR                  11 document?                  12 A. Yes. That's on page --                  13 Q. They're alphabetical, aren't                  14 they?                  15 A. Yeah. That's on page 5 of 11 in                  16 that document. It's any component other than the                  17 active ingredient.                  18 Q. Is that what it says?                  19 A. That's what it --                  20 Q. Can you read it verbatim?                  21 A. "Inactive ingredient is any                  22 component other than active ingredient."                  23 So that would cover contaminants,                  24 impurities, excipients, or whatever.                  25 Q. It refers to specifically the</p>	<p style="text-align: right;">Page 248</p> <p>1 it's uncommon when companies are making generic                  2 products, sometimes on the first run, to have                  3 something that ends up not being bioequivalent and                  4 requires going back to the drawing board and                  5 altering particle size or some other component of                  6 the formulation until they -- until they get the                  7 product that is going to be bioequivalent that                  8 would then be FDA approved, the ANDAs approved,                  9 and then it's allowed to be given to patients as                  10 an AB-rated generic drug.                  11 That's not, I don't believe,                  12 uncommon. I don't have statistics on that, but I                  13 think it's unrealistic to expect them to get it                  14 right on the first time every single time. And                  15 those are -- as long as those are disclosed to the                  16 FDA that we made this change and now we want this                  17 approved, and then the FDA approves it. And so                  18 all the ANDAs that I -- I included in my report                  19 were FDA reviewed, approved, AB-rated and allowed                  20 to be generically substituted for a brand name                  21 valsartan product.                  22 Q. Did any of the BE documents, even                  23 including the failed ones that counsel showed you,                  24 did any of those show that the valsartan's                  25 bioequivalence was affected by the presence of</p>
<p style="text-align: right;">Page 247</p> <p>1 components, doesn't it?                  2 A. Yes.                  3 Q. Can you read the definition for a                  4 Component?                  5 MR. VAUGHN: May the record                  6 reflect as the Defense counsel                  7 repeatedly objected to any type of                  8 regulatory questions or opinions and now                  9 is solely focussed on regulatory                  10 questions.                  11 THE WITNESS: "Component is any                  12 ingredient intended for use in the                  13 manufacture of a drug product, including                  14 those that may not appear in such drug                  15 product."                  16 So that could be a lot of                  17 excipients and those kinds of things.                  18 BY MR. FOWLER:                  19 Q. Thank you.                  20 Doctor, have you seen anything in                  21 the documents that -- that Plaintiffs' counsel has                  22 shown you today with regard to the ANDAs or the                  23 bioavailability studies that change -- change any                  24 of your opinions in this case?                  25 A. No. And -- and I don't think</p>	<p style="text-align: right;">Page 249</p> <p>1 other compounds, whether they be, you know,                  2 amlodipine, HCTZ or the combination thereof?                  3 A. Yeah, again, we don't know which                  4 did or didn't have NDMA, but inclusion of the                  5 combination products was demonstrated to support a                  6 scientific conclusion that without an overlapping                  7 either metabolism or drug distribution system,                  8 that those compounds in with valsartan, even in                  9 milligram quantities, much less microgram                  10 quantities, would not be expected to have any                  11 altering effect on the bioequivalence, and                  12 therefore the therapeutic response to valsartan.                  13 Q. Regard to -- I'm showing you what                  14 was marked as Exhibit 19. This, I'll refer to it                  15 as the bankruptcy document with regard to PRACS.                  16 Is there any mention of valsartan or valsartan                  17 testing anywhere in that document?                  18 A. No.                  19 Q. With regard to the -- with regard                  20 to Exhibit 20, Doctor, do you recall the -- the                  21 questions concerning Cetero's bioequivalence data                  22 and FDA's investigation of that?                  23 I'm showing you 20 -- Exhibit 20.                  24 Do you recall those questions, the questions on                  25 the document?</p>



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1 A. Yes.  
2 Q. Can you turn to the second page  
3 and identify what are the drugs that those ANDAs  
4 of reference in that Exhibit 20, what are those  
5 drugs?  
6 A. Federal Register Notices on  
7 October 28th. "The agency is proposing to  
8 withdraw Watson's Oxycodone/ibuprofen ANDA and  
9 InvaGen's Trandologril (phonetic) ANDA."  
10 Q. Is there anything in that  
11 document that suggests FDA was critical of any  
12 testing of the valsartan bioequivalence, if any  
13 was done at all at that -- by that company at that  
14 location?  
15 A. No mention of valsartan at all.  
16 Q. Doctor, can you explain why it is  
17 that you spent the time reviewing the BE data from  
18 each of the various generic manufacturers for the  
19 various drugs, whether it's valsartan by itself or  
20 in combination? What was the im- -- what was the  
21 importance? What was -- why did you review those  
22 -- that data, and how did it factor into your  
23 opinion?  
24 MR. VAUGHN: Object to the form.  
25 THE WITNESS: Again, from a pure

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1 scientific standpoint, if two compounds  
2 that are known to be in the same tablet,  
3 let's say, have the chance to interfere  
4 with each other altering the effect of  
5 certainly the intended compound, in this  
6 case valsartan, then I wrote a -- a  
7 fairly lengthy section in my report  
8 about what are the different mechanisms  
9 whereby there would be an interruption  
10 of the valsartan effectiveness. It had  
11 to be its absorption, it had to be its  
12 metabolism, it had to be its hepatic  
13 distribution, or its effect at the  
14 angiotensin II receptor site.  
15 And there's no mechanism whereby  
16 NDMA or NDEA can do that. There's no  
17 mechanism whereby hydrochlorothiazide,  
18 which is in there, can do that. And  
19 there is no mechanism where amlodipine  
20 does that. So none of those substances  
21 have any mechanisms to alter either the  
22 kinetics or the therapeutic response to  
23 valsartan.  
24 BY MR. FOWLER:  
25 Q. You were shown -- let me, for

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1 example, hand you Exhibit 14 -- hand you  
2 Exhibit 14 (tendering) -- and direct your  
3 attention to the table showing the BE results.  
4 Let me know when you're there.  
5 A. I'm there.  
6 Q. The BE results were outside of  
7 the 80 to -- is it 120 is the FDA range?  
8 A. 125.  
9 Q. When they are -- when the BE  
10 results as reflected there in Exhibit 14 were  
11 outside the range, do you attribute any of that to  
12 any presence of NDMA or NDEA?  
13 A. No. Again, this is usually due  
14 to some type of tableting issue and -- and  
15 particle size. So it's -- it's -- I would not  
16 attribute it to NDEA or NDMA at all.  
17 Q. Based on your understanding of  
18 the science of the bioequivalence study process,  
19 can you explain what reformulation does and how  
20 that would translate to different results of the  
21 BE studies?  
22 MR. VAUGHN: Object to the form.  
23 THE WITNESS: Yeah, again, this  
24 starts getting into a pharmaceuticals  
25 process that's a little bit -- I've had

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1 a little bit of training in that and --  
2 and understanding and have read some  
3 articles throughout the years.  
4 But it's mostly involving the --  
5 the tableting, the particle size, the  
6 pressure with which you compress the  
7 tablet, the film coating, the things  
8 that result in the tablet disintegrating  
9 and then releasing the active  
10 ingredient.  
11 And so it's -- it's more of a  
12 pharmaceuticals development, tinkering  
13 that you do with your products to get  
14 the intended dissolution and then  
15 ultimate bioequivalence that you're  
16 looking for.  
17 BY MR. FOWLER:  
18 Q. Does the fact that some of the  
19 studies, the BE studies you were shown by counsel,  
20 were studies under 100 percent males and 100  
21 percent Asian males, does that have any impact on  
22 -- first of all, on the validity of the BE  
23 results?  
24 A. No. Again, the FDA allowed those  
25 studies to be done and approves the ANDAs in the

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1 face of those. And remember, what you're doing  
 2 with the bioequivalence study in the same person  
 3 is comparing test product with reference products.  
 4 And then you take it to another  
 5 person and you test, test product versus reference  
 6 product. And the fact that that, both times, was  
 7 in a male or that they weighed 60 kilograms, if  
 8 you then take that same release characteristic to  
 9 a female or a person that weighs 78 kilos or a  
 10 person that's 39 instead of 29, you're still  
 11 within that same person going to see the -- the  
 12 approvable release characteristics in that --  
 13 between those two products. It'll retain its  
 14 bioequivalence.  
 15 Q. Do the test subjects or the test  
 16 methodology of the BE studies, that you were  
 17 shown, impact your opinion with regard to the  
 18 presence of NDMA and its impact, if any, on  
 19 bioequivalence?  
 20 A. I think it's --  
 21 MR. VAUGHN: Object to form.  
 22 THE WITNESS: -- a similar  
 23 question worded slightly -- I'm sorry,  
 24 go ahead.  
 25 MR. VAUGHN: I -- object to form.

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1 You're good.  
 2 THE WITNESS: Okay. I think it's  
 3 a similar question asked a slightly  
 4 different way, and -- and as I've stated  
 5 multiple times today -- and it's in my  
 6 report -- the presence of NDMA and NDEA,  
 7 there's no mechanism, no scientific  
 8 rationale beyond how they could alter  
 9 the bioequivalence of any of the  
 10 valsartan products.  
 11 BY MR. FOWLER:  
 12 Q. Would that be true for either  
 13 gender or any race, in your opinion?  
 14 A. Yeah, that's -- would be  
 15 independent of those issues.  
 16 Q. Early in the deposition, there  
 17 were questions about the circulation of -- of  
 18 blood.  
 19 Do you recall those questions?  
 20 A. Uh-huh. Yes. Sorry.  
 21 Q. And does -- how, if at all, does  
 22 the blood circulation play a role in your opinions  
 23 in this case with regard to the NDMA and -- and  
 24 the valsartan?  
 25 MR. VAUGHN: Object to form.

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1 THE WITNESS: In -- in the  
 2 context that we were talking about at  
 3 that time, we were talking about the  
 4 ability to measure an elimination  
 5 half-life and how that's affected by  
 6 blood flow, liver blood flow. You can  
 7 only measure that if there's drug in the  
 8 blood. And with NDMA at the amounts  
 9 that we're talking about, that has to be  
 10 given intravenously, and then you can  
 11 measure the decline in blood because it  
 12 started there and you watch it go down.  
 13 And some of that blood flow goes to the  
 14 liver, some goes to the heart, some goes  
 15 to the lungs, you know, whatever.  
 16 That issue doesn't apply when you  
 17 talk about giving low doses of these  
 18 high-clearance drugs in an oral format  
 19 that don't reach the systemic  
 20 circulation. You can't measure a  
 21 half-life in a situation where there's  
 22 no measurable drug there to begin with.  
 23 BY MR. FOWLER:  
 24 Q. Doctor, directing your attention  
 25 to your report. Do you have that in front of you?

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1 A. I do.  
 2 Q. Has counsel asked you about all  
 3 of your opinions in your report today?  
 4 A. Pretty much focussed on -- on  
 5 bioequivalence, I would say.  
 6 Q. Do you have -- turning your  
 7 attention to page 52. Do you see a Summary of  
 8 Opinions and Conclusions section?  
 9 A. Yes.  
 10 Q. Would you please read both of  
 11 those points on page 52 going over to 53 to the  
 12 third point, please?  
 13 A. Okay. There are three main  
 14 points that I addressed in -- in my report, and  
 15 they're -- they're summarized on the end of page  
 16 52 and at the beginning of page 53.  
 17 The first is relevant to what we  
 18 had a lot of questions on today, and it basically  
 19 is that the presence of NDMA and NDEA in valsartan  
 20 could not have had any effect on the kinetics,  
 21 dynamics, bioavailability or bioequivalence of  
 22 valsartan generic products because there's --  
 23 Q. Just please -- just read your --  
 24 read from your paragraph, please.  
 25 A. Oh, read it verbatim?

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1 Q. Yes, sir.  
 2 A. I'm sorry.  
 3 Q. You were doing fine.  
 4 A. "The compounds do not share any  
 5 known pharmacokinetic or pharmacodynamic  
 6 mechanism. The presence of active intended  
 7 ingredients with valsartan, such as  
 8 hydrochlorothiazide or amlodipine, also did not  
 9 alter valsartan bioequivalence for the same  
 10 reasons, so there is no overlapping  
 11 pharmacokinetic process. Thus, there is no  
 12 conceivable way for NDMA or NDEA, merely by being  
 13 present, to alter the bioequivalence of valsartan,  
 14 and thus its therapeutic response and efficacy."  
 15 Q. Thank you. And you have another  
 16 opinion?  
 17 A. And my second opinion gets back  
 18 to this concept of first pass metabolism. "The  
 19 levels of NDMA or NDEA that the FDA has detected  
 20 in affected valsartan tablets, when these are  
 21 taken on a daily basis, would not exceed the  
 22 liver's capacity to metabolize the NDMA or the  
 23 NDEA contained in those tablets in a first pass  
 24 metabolism process. And according-" --  
 25 "accordingly, NDMA or NDEA is unlikely to reach

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1 the systemic circulation or other organ systems  
 2 outside of the liver; therefore, there is no  
 3 scientific basis to assume that there is any  
 4 increased risk to other organ systems which  
 5 support the medical monitoring that is proposed by  
 6 Plaintiffs' expert Dr. Kaplan."  
 7 Q. Thank you.  
 8 And on the -- on the next page,  
 9 do you have another opinion?  
 10 A. I have another opinion, and --  
 11 and this was more of a mathematical. "Based on  
 12 the known pharmacokinetic principles of  
 13 accumulation, the daily exposure" -- which in this  
 14 case is usually every 24 hours -- "to NDMA or NDEA  
 15 would not accumulate, given the known elimination  
 16 half-life of these compounds, which are in" --  
 17 "measured in minutes."  
 18 So to give something that's gone  
 19 in three to five half-lives, of a five- to  
 20 ten-minute elimination rate, there's no way, given  
 21 that once every 24 hours, could lead to any type  
 22 of accumulation at all.  
 23 Q. Do you hold those opinions to a  
 24 reasonable degree of medical -- of scientific  
 25 certainty?

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1 A. Yes.  
 2 Q. We also marked --  
 3 MR. FOWLER: I think we're up to  
 4 Exhibit 37 [sic], Counsel.  
 5 BY MR. FOWLER:  
 6 Q. -- simply the list of materials  
 7 considered that was provided to you. I just  
 8 wanted to mark that as an exhibit.  
 9 (Exhibit 38 was marked.)  
 10 BY MR. FOWLER:  
 11 Q. Doctor, do you recognize that as  
 12 your Materials Considered list?  
 13 A. Yes.  
 14 Q. And then Exhibit 38 [sic] is --  
 15 MR. FOWLER: Counsel, I'm holding  
 16 up the flash drive of Dr. Bottorff's  
 17 Materials Considered. So we're going to  
 18 send this to the court reporter as we've  
 19 done in other depositions and be copied  
 20 that way.  
 21 This is Exhibit 38 [sic]. Madam  
 22 Court Reporter, we'll mail that to you.  
 23 (Late-filed Exhibit 39 was  
 24 marked.)  
 25 BY MR. FOWLER:

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1 Q. If you'll indulge us for a  
 2 moment, I may be about finished.  
 3 My much more attentive colleague  
 4 has pointed out that the Materials Considered is  
 5 38 and the flash drive should be 39, so we'll just  
 6 fix that.  
 7 And with that, I'll -- I'll -- I  
 8 have no further questions.  
 9 Thank you very much, Doctor.  
 10 MR. FOWLER: Counsel.  
 11 MR. VAUGHN: Can you just give me  
 12 five minutes to consult with my  
 13 cocounsel? I'll be right back. We'll  
 14 be real quick.  
 15 THE VIDEOGRAPHER: Shall we go  
 16 off the record?  
 17 MR. VAUGHN: Please.  
 18 THE VIDEOGRAPHER: The time is  
 19 4:51 p.m. We're off the record.  
 20 (Brief recess observed.)  
 21 THE VIDEOGRAPHER: 4:56 p.m.,  
 22 we're back on the record.  
 23 EXAMINATION  
 24 BY MR. VAUGHN:  
 25 Q. Dr. Bottorff, do all of your

<p style="text-align: right;">Page 262</p> <p>1 opinions contained within your class action expert                  2 report apply equally to all potential class                  3 members?                  4 A. I'm not sure exactly what that                  5 question means. What -- what -- what does that                  6 mean exactly so I can better answer it?                  7 Q. Which part of the question are                  8 you having trouble with?                  9 A. Well, maybe start with the                  10 definition of the class members. Are they the                  11 people who have filed, like, claims or....                  12 Q. I -- I understand now, Doctor.                  13 Do all of your opinions contained                  14 within your class action expert report apply                  15 equally to all of the Defendants?                  16 A. Again, I don't know if I had                  17 bioequivalence data on -- well, from every                  18 Defendant, but I -- I think it does because of the                  19 reasons behind it. It doesn't matter that NDMA                  20 may have been in there or not. It wouldn't affect                  21 the bioequivalence. So I guess I would say yes.                  22 Q. As a pharmacist, if you are in                  23 possession of an adulterated drug, would you                  24 return that adulterated drug to a manufacturer, or                  25 would you just throw it away?</p>	<p style="text-align: right;">Page 264</p> <p>1 destruction process that is not flushing                  2 them down the toilet. So that's just                  3 not how it happens these days.                  4 BY MR. VAUGHN:                  5 Q. All right. Regardless, you                  6 wouldn't be able to sell the contaminated drugs,                  7 correct?                  8 MR. FOWLER: Objection: Form,                  9 outside the scope of his report and his                  10 testimony and the redirect.                  11 THE WITNESS: Yeah, I -- again,                  12 in -- in your hypothetical, you would                  13 have to know that something was                  14 adulterated, so I don't -- I don't know                  15 what that process is.                  16 BY MR. VAUGHN:                  17 Q. As a pharmacist, if the FDA would                  18 not let you sell a drug to the U.S. public, what                  19 would you do? Would you be able to get your money                  20 back from the manufacturer?                  21 MR. FOWLER: Objection, form.                  22 This is outside the scope of his                  23 entire report, of his testimony, and                  24 outside of my redirect. Nothing about                  25 The redirect opened up questions for</p>
<p style="text-align: right;">Page 263</p> <p>1 MR. FOWLER: Objection: Form,                  2 scope.                  3 THE WITNESS: I've never been in                  4 that position of -- in -- in that type                  5 of practice. I guess I would follow                  6 whatever my -- my company's policy was.                  7 But I don't -- I don't know what that                  8 is. I don't know what that would be.                  9 BY MR. VAUGHN:                  10 Q. Would you be afraid of                  11 contaminating the groundwater if you're just                  12 throwing away drugs that are contaminated with                  13 carcinogens?                  14 MR. FOWLER: Objection, outside                  15 the scope of my redirect completely.                  16 MR. VAUGHN: Your redirect had                  17 him answer quest- -- testifying on every                  18 single one of his opinions. You                  19 completely opened the scope up.                  20 THE WITNESS: Well, what I can                  21 answer is that that's not how in                  22 pharmacies that we get rid of drugs                  23 anymore. There are drug take-back                  24 programs that almost every pharmacy runs                  25 periodically, and there's some</p>	<p style="text-align: right;">Page 265</p> <p>1 what a pharmacist is going to sell,                  2 Counsel.                  3 MR. VAUGHN: He -- he submitted                  4 an expert report in a class action                  5 saying this stuff is worth money.                  6 MR. FOWLER: You should have                  7 asked him about that in your case in                  8 chief here on -- on direct. You're                  9 going back, for whatever reason. It's                  10 outside the scope, and I would have                  11 objected to it in the first place.                  12 MR. VAUGHN: You did object to it                  13 a bunch in the first place and then you                  14 were coaching the witness before and                  15 then you opened everything back up by                  16 having him read every one of his                  17 opinions. You opened the scope.                  18 MR. FOWLER: I'm not going to                  19 argue with you, Counsel. The words                  20 "sell the drugs" was nowhere in his                  21 opinions.                  22 BY MR. FOWLER:                  23 Q. If you can't sell a drug --                  24 (Unintelligible overlapping.)                  25 BY MR. VAUGHN:</p>

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1 Q. -- Doctor, does it have any  
2 value?  
3 MR. FOWLER: I'm sorry, I spoke  
4 over you, Counsel. Please state that  
5 again.  
6 THE WITNESS: Or I -- I never  
7 answered the previous question.  
8 MR. FOWLER: He withdrew.  
9 THE WITNESS: Oh, okay.  
10 MR. FOWLER: So a new question.  
11 Go ahead.  
12 BY MR. VAUGHN:  
13 Q. Would you like to answer the  
14 previous -- would you like to answer the previous  
15 question, Doctor?  
16 A. If you would like me to.  
17 Q. So as a pharmacist, if the FDA  
18 will not allow you to sell a drug to the U.S.  
19 public, would you be able to get your money back  
20 from the manufacturer?  
21 MR. FOWLER: Same objection.  
22 THE WITNESS: And I would say  
23 that I've never been in the situation to  
24 understand how that works. That's not  
25 my -- my academic career has been

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1 working in hospitals with cardiology  
2 patients and cardiologists, and I've  
3 never worked in that environment, so I  
4 -- I had no experience with that at all.  
5 BY MR. VAUGHN:  
6 Q. If you can't sell the drug,  
7 Doctor, does the drug have any value?  
8 MR. FOWLER: Form,  
9 incomprehensible.  
10 THE WITNESS: Again, I -- I mean,  
11 in a hypothetical, if you can't sell it,  
12 then obviously you can't sell it, so....  
13 BY MR. VAUGHN:  
14 Q. Absolutely.  
15 A. So I would say, yeah, if you  
16 can't sell it -- so it doesn't have value if you  
17 can't sell it.  
18 MR. VAUGHN: I have no further  
19 questions.  
20 MR. FOWLER: He'll read.  
21 MR. VAUGHN: Thanks for your time  
22 again, Dr. Bottorff.  
23 MR. FOWLER: Nothing further.  
24 THE VIDEOGRAPHER: The time is  
25 5:02 p.m. This concludes today's

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1 testimony from Dr. Michael Bottorff.  
2 We are now off the record.  
3 FURTHER DEPONENT SAITH NOT.  
4 (Proceedings concluded at 4:02  
5 p.m. Eastern.)  
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1 REPORTER'S CERTIFICATE  
2 I certify that the witness in the  
3 foregoing deposition, MICHAEL BOTTORFF, PHARM.D.,  
4 was by me duly sworn to testify in the within  
5 entitled cause; that the said deposition was  
6 taken at the time and place therein named; that  
7 the testimony of said witness was reported by me,  
8 a Shorthand Reporter and Notary Public of the  
9 State of Tennessee authorized to administer oaths  
10 and affirmations, and said testimony, Pages 7  
11 through 258 thereafter transcribed into  
12 typewriting.  
13 I further certify that I am not of counsel  
14 or attorney for either or any of the parties to  
15 said deposition, nor in any way interested in the  
16 outcome of the cause named in said deposition.  
17 IN WITNESS WHEREOF, I have hereunto set my  
18 hand this 4th day of April 2022.  
19  
20  
21  
22  
23  
24  
25

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Carissa L. Boone, LCR No. 382  
My License Expires: 6/30/2022



ERRATA

I, MICHAEL BOTTORFF, PHARM.D., having read the foregoing deposition, Pages 7 through 268, taken March 25, 2022, do hereby certify said testimony is a true and accurate transcript, with the following changes (if any):

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\_\_\_\_\_  
MICHAEL BOTTORFF, PHARM.D.

\_\_\_\_\_  
Notary Public

My Commission Expires: \_\_\_\_\_



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